cobas® 6000 analyzer series

Operator's Manual

Roche

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05581435005

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Revision History

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Publication Reference Number	Date	Revision purpose
05581435001 Version 2.0	May 2009	Software update
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05581435003 Version 5	October 2010	Updates to manual.
05581435004 Version 6.0.1	March 2014	Revised for software version 05-02.
05581435005 Version 7.1	May 2015	Revised for software version 06-01

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As the need arises, you shall receive various customer communications concerning information about your system. These updates are usually in one of the following forms:

- *Bulletins* – Bulletins (Reagent, Software, or Analyzer) are printed on Roche Diagnostics letterhead. Bulletins contain information that is vital to the performance of your system. Bulletin information should be communicated internally to all analyzer operators. Bulletins should be kept on file until the reagent expires, you receive updated labeling or you are notified by Roche Diagnostics to discard them.
- *Urgent Medical Device Correction or Removal* – Urgent Medical Device Correction or Removal is printed on Roche Diagnostics letterhead with the words **Urgent Medical Device Correction** or **Urgent Medical Device Removal**. These require immediate attention by the analyzer operator and are to be filed for reference until further notice.
- *Customer Letters* – Customer Letters are printed on Roche letterhead and contain general information or attachments that you may place in your files. You may discard Customer Letters after reading and following any applicable instructions contained in them.
- *Product Announcement* – Product Announcements are usually announcing product launches. They contain specific details about a new product such as features and benefits, kit configuration and pricing. Product Announcements may or may not be discarded depending on your laboratory's preference.

Customer communications can also be viewed on the internet. Some documentation is available online only. Go to http://www.usdiagnostics.roche.com and select **Documentation**.

CLIA/CLSI Compliance

Roche documentation, which includes this operator's manual, methods sheets and active customer bulletins, conforms with the guidelines in effect at the time of publication listed in the Code of Federal Regulations (CFR) and the Clinical Laboratory Standards Institute (CLSI) General Laboratory Practices and Safety Guidelines. Documentation also meets the Health Care Financing Administrations (HCFA) interpretation of the requirements for the Clinical Laboratory Improvement Amendments (CLIA '88).

Contacting Commercial Education

The documentation you receive to operate your system, prepare and/or utilize reagents, is created by several departments within Roche. The Commercial Education department produces most of the training documentation you receive here in Indianapolis, or at your on-site training. To reach Commercial Education, you may:

- send an email to Indianapolis.TechPub@roche.com
- leave a message by calling 1-800-845-7355, mailbox #26699.

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If you have any questions on documentation that is not of a training nature, look to the beginning of the document for information or contact the Customer Support Center at **1-800-428-2336.**

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- leave a message by calling 1-800-845-7355, mailbox #26699
- go to www.usdiagnostics.roche.com > Contact > Contact Change Form.

Please provide your name and account number when contacting us. Your account number is provided to you by a Roche representative when your analyzer is installed.

cobas® 6000 analyzer series

Operator´s Manual and
Software Description
Software Version 06-01

Document information



General attention

It is important that the operator read the Operator´s Manual thoroughly before using the instrument.

- Pay particular attention to all safety precautions.
- Always follow the instructions in the Operator´s Manual. Do not use the instrument in a way that is not described in the Operator´s Manual.
- Keep the Operator's Manual in a safe place to ensure that it is not damaged and remains available for use. This manual must be easily accessible at all times.

Revision history

Manual version	Software version	Revision date	Changes
1.0	01-01	June 2006	
1.1	02-01	September 2007	General update
2.0	02-01 – 02-07	March 2008	General update
3.0	03-01	June 2008	General update
4.0	04-01	February 2009	General update
5.0	05-01	March 2010	General update
5.1	05-01	April 2011	Two safety alerts added
6.0	05-02	July 2013	General update
6.0.1	05-02	March 2014	Minor changes concerning expired reagents and controls
7.0	06-01	December 2014	General update
7.1	06-01	January 2015	Minor changes

Edition notice

Operator´s Manual and Software Description of the **cobas** 6000 analyzer series.

This document is for users of the **cobas** 6000 analyzer series.

Every effort has been made to ensure that all the information contained in this document is correct at the time of printing. However, Roche Diagnostics GmbH reserves the right to make any changes necessary without notice as part of ongoing product development.

Any customer modification to the instrument will render the warranty or service agreement null and void.

Software updates are done by the Roche service representative.

Intended use

The **cobas** 6000 analyzer series is a fully automated system for immunological and clinical chemistry analysis intended for the in vitro quantitative/qualitative determination of analytes in body fluids.



Improper use of the instrument can result in serious injury.

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Instrument approvals

The **cobas** 6000 analyzer series meets the protection requirements laid down in IVD Directive 98/79/EC. Furthermore, our instruments are manufactured and tested according to the following international standards:

- IEC 61010-1: 2001
- IEC 61010-2-010: 2003
- IEC 61010-2-081: 2001
- IEC 61010-2-101: 2002
- UL 61010-1: 2nd edition
- CAN/CSA 61010-1: Second edition

The **cobas** 6000 analyzer series complies with the emission and immunity requirements described in the following standard:

- IEC 61326-2-6: 2005

The Operator's manual meets the European Standard DIN EN ISO 18113-3.

Compliance is demonstrated by the following marks:

CE — Complies with the IVD directive 98/79/EC.

c UL us — Issued by Underwriters Laboratories, Inc. (UL) for Canada and the US.

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Table of contents

Document information 2
Contact addresses 4
Preface 9
Where to find information 9
Customer information 10
Online Help system of the instrument 10
Videos in the Online Help system of the instrument 11
Conventions used in this manual 11

System description Part A

1 General safety information
Safety classifications A–5
Safety precautions A–6
Safety labels of the system A–22
Safety information for barcode readers A–30
Interlock function A–31
Disposal of the instrument A–32

2 Overview modules
Overview A–35
Modules of the **cobas** 6000 analyzer series A–36

3 Control unit, cobas link and core unit
Control unit A–45
cobas link A–47
Core unit **cu** 150 A–52
Trays, racks, tubes, and cups A–59

4 c 501 module
Overview A–67
Sampling area components A–70
Reagent area components A–72
Reaction disk area components A–77
Behind the front doors A–86
Rear view A–88
ISE area components A–89

5 e 601 module
Overview A–95
Reagent area components A–97
Reaction area components A–99
Pre-wash area components A–101
Consumables area components A–103
Auxiliary reagents and cleaning solutions A–106

6 Specifications
General system specifications A–111
Control unit A–118
Core unit **cu** 150 A–118
c 501 module A–119
e 601 module A–122

Operation Part B

7 Software basics
General description of the user interface B–5
The help system of the instrument B–13
Main menus B–21

8 Daily operation
Overview B–29
Starting the analyzer B–30
Preroutine operation B–43
Routine operation B–61
Shutting down the analyzer B–74

9 Orders and results
Overview B–79
Test Selection screen B–80
Data Review screen B–88
Calib. Review screen B–96
Tracking samples on the analyzer B–98

10 Reagents
Reagent concept – **c** 501 B–105
Reagent concept – **e** 601 B–114
Operator-related reagent management B–124
Reagent Setting screen B–125
Reagent Status screen B–130
Reagent Overview button B–141

11 Calibration
Calibration concept B–155
Calibration concept – **c** 501 B–158
Calibration concept – **e** 601 B–162
Calibration concept – masking B–165
Overview B–166
Calibration Status screen B–166
Calibration Calibrator screen B–178
Calibration Install screen B–181
System Overview screen B–194

12 QC
QC concept B–197
Overview B–202
QC Status screen B–202
QC Run Status screen B–207
QC Individual screen B–209
QC Cumulative screen B–217
QC Control screen B–218
QC Install screen B–220
Automatic QC measurement B–228

13 Extended operation
Instrument status B–233
Interlock function: Reset after stop B–235
Masking functions B–236
Backup operation B–240
Data storage B–244

14 Configuration
Application B–251
Description of application parameters B–260
System configuration B–277
Module Set B–287
Calculated Tests (**c** 501) B–291
Special Wash B–297
Report Format B–306
Saving system parameters B–310
Restoring system parameters B–312

Maintenance Part C

15 General maintenance
Overview C–5
Maintenance pipes C–10
Maintenance types C–18
Maintenance report C–22
Maintenance schedules C–23
Automating instrument care with maintenance pipes C–32
Background and parallel maintenance C–34
List of maintenance items C–38
List of maintenance checks C–43

16 Maintenance cu 150
Maintenance schedule C–49
Daily maintenance C–50
Monthly maintenance C–53
Every six months maintenance C–58
As needed C–61

17 Maintenance c 501 with ISE
Maintenance schedule C–65
Periodic replacement of parts C–67
Daily maintenance C–68
Weekly maintenance C–77
Monthly maintenance C–84
Every three months maintenance C–98
Every six months maintenance C–101
As needed maintenance C–106

18 Maintenance e 601
Maintenance schedule C–117
Daily maintenance C–118
Weekly maintenance C–121
Every two weeks maintenance C–137
Every three months maintenance C–140
As needed C–143

Troubleshooting Part D

19 Data alarms
Introduction D–7
Data alarm list D–10
Data alarms **c** 501 (ISE) D–12
Data alarms **c** 501 (P) D–20
Data alarms **e** 601 module D–32
Data alarms for calibrations D–43
Data alarms for controls D–55
Data problems without alarm D–60
Rerun list D–63

20 Troubleshooting
General troubleshooting D–67
Instrument troubleshooting D–70
c 501 (ISE) troubleshooting D–74
c 501 (P) troubleshooting D–78
e 601 troubleshooting D–85

Software description Part E

21 System overview
System Overview screen E–5
Sample Data Clear window E–11
Reagent Preparing window E–12
Calibration and QC Select window E–13
To Do List window E–16
Sample Tracking window E–17
Sample Search window E–24
Backup Operation window (**c** 501 module) E–26
Reagent Overview window (**c** 501 module) E–27
Reagent Overview window (**e** 601 module) E–32
Detail window E–37
Inventory Update window E–47
Temperature window (**e** 601 module) E–48

22 Global screens
Overview E–55
Stop screen E–58
Shut Down screen E–59
Sleep window E–61
Logon screen E–63
S. Stop screen E–64
Alarm screen E–65
Sound Setting window E–67
Print screen E–68
Print View window E–70
Jump window E–72
Print window E–73
Media Write window E–74
Reports E–75
Workplace print screen E–77
Reagent Information print screen E–99
Calibration print screen E–107
QC print screen E–129
Utility print screen E–149
Reports Printed from Utility > Maintenance E–179
Start Conditions screen E–186
Pipe Function window E–190
Automatic Rerun window E–191
Host Setting window E–192
Rack Reception Mode window E–193
MPA Connection Mode window E–194
Masking window E–195
Module Masking window E–197
Default Profile Per Sample Type window E–198
Confirmation window E–199
No Help available E–199

23 Workplace menu
Test Selection screen E–203
Demographics window E–211
Barcode Read Error window (barcode mode) E–213
Rerun Rack Assignment window (non-barcode mode) E–214
Repeat Test Selection window (non-barcode mode) E–215
Data Review screen E–216
Read Backup Disk window E–222
Search Sample window E–223
Filter window E–225
Send To Host window E–227
Delete All window E–229
Backup Data window E–230
Test Review window E–232
Detail window E–238
Manual Test window E–239
Reaction Monitor window E–240
Scale Setting window E–242
Overlay window E–243
Calib. Review screen E–245

24 Reagent menu
Setting screen E–251
Manual Registration window (**e** 601 module) E–255
Reagent Prime window E–256
Cassette Unloading window E–257
Open Channel window E–258
Status screen E–259
Inventory Setting window E–264
Confirmation window E–264

25 Calibration menu
Status screen E–267
Calibration Trace window E–271
Scale Setting window – Calibration Trace E–275
Comment window – Calibration Trace E–276
Calibration Result (ISE) window E–277
Calibration Result (Photometry) window E–279
Calibration Result (Immune) window E–282
Working Information window (**c** 501) E–284
Scale Setting window – Working Information E–286
Calibration Factor window (**c** 501) E–287
Reaction Monitor window (**c** 501) E–289
Scale Setting window – Reaction Monitor E–291
Instrument Factor window E–292
Start Up Setting window E–294
Calibrator screen E–296
Calibrator Rack Assignment window E–298
Install screen E–300
Assignment window E–302
Download window E–303
Confirmation window (calibrator download) E–305
Edit Calibrator window (**c** 501 only) E–307

26 QC menu
Status screen E–311
Routine QC window E–313
Stand By Bottle QC window E–314
Automatic QC Unloading window E–316
Run Status screen E–317
Individual screen E–320
Individual QC Chart window E–322
Comment window E–325
Select Chart window E–326
Realtime QC window E–327
Accumulate Data window E–330
Select Control window E–331
Select Rules window E–332
Reject Data window E–333
Cumulative screen E–334
Cumulative QC Chart window E–336
Select Chart window E–339

Control screen E–340
QC Rack Assignment window E–342
Install screen E–344
Add Control window E–347
Download window E–348
Edit Control window E–351

27 Utility menu
System screen E–361
Rack Assignment window E–367
False bottom/Cup on non-standard tube Setting window E–372
Barcode Setting window E–373
Alarm Setting window E–374
Host Communication Setting window E–376
Host Test Code Setting window E–382
Comment Title window E–383
Key Setting window E–384
Key Setting window E–385
Profile Setting window E–386
QC Setting window E–387
Reagent Level Check window E–388
Calibration Mask Setting window E–392
Maintenance Setting window E–393
Edit Maintenance Type window E–394
User Definable window E–396
Maintenance Pipe Setting window E–397
Edit Pipe window E–398
Power Up Pipe Setting window E–400
Operator ID Setting window E–402
Add Operator ID window E–403
Check Digit window (barcode mode) E–410
ISE Calibration Setting window E–411
Rack Delivery window E–412
Dilution and Cleaner Cassette Setting window (**c** 501) E–415
Bottle Setting window E–417
Automatic Printout Setting window E–418
Review By Exception window E–419
Maintenance screen E–420
Maintenance Monitor window E–422
Maintenance items E–423
Maintenance checks E–466
Application screen E–484
Application Parameter Delete window E–514
Download window E–515
Calculated Test screen E–520
Calculated Test Formula window E–523
Compensated Test Formula window E–527
Special Wash screen E–528
Report Format screen E–540
Module Set screen E–544
Test Assignment E–545
c501 Test Assignment(C Module) E–546
e601 Test Assignment(E Module) E–547
Module Setting E–549

Glossary **Part F**

Index **Part G**

Notes **Part H**

Preface

The **cobas** 6000 analyzer series is a fully automated, random-access, software-controlled system for immunoassay and photometric analysis intended for qualitative and quantitative in vitro determinations using a wide variety of tests. The **cobas** 6000 analyzer series is a powerful tool for complete diagnostic laboratory automation. It is optimized for high throughput workloads using a combination of an ion selective electrode (ISE) and photometric analysis (**c** 501 module), and an immunoassay analysis module (**e** 601 module).

This manual has detailed descriptions of features of the **cobas** 6000 analyzer series and general operational concepts, specification functions and use of controls, operating techniques, emergency procedures, product labeling and maintenance procedures.

Observe the instructions of the Operator's Manual for safe operation of the system

- If the system is used in a manner not specified in this Operator's Manual, the protection provided by the system may be impaired.
- Keep this manual in a safe place to ensure that it is not damaged and remains available for use.
- This Operator´s Manual should be easily accessible at all times.

Where to find information

The following documents are provided to assist in finding desired information quickly:

Operator's Manual Contains information about safety, hardware modules and operating the system as well as maintenance and troubleshooting. A table of contents at the beginning of the book and each chapter, and an index at the end of this book help you to find information quickly.

Online Help Contains a detailed description of the software of the **cobas** 6000 analyzer series. In addition to the software description, the whole Operator's Manual is embedded into the Online Help. This makes it possible to retrieve information from both Online Help and Operator's Manual using the search functions available for electronically stored documents.

COBI-CD The COBI-CD (Compendium of Background Information) provides you with background information about the technologies, test principles, their theory and calibration methods used by the **cobas** 6000 analyzer series. It also provides a complete glossary. The information can be read and printed using Adobe Acrobat Reader.

You cannot use the COBI-CD on the control unit of the analyzer because the COBI-CD requires Adobe Acrobat Reader to be viewed correctly. Adobe Acrobat Reader is not installed on the control unit and must not be installed.

Customer information

Customer training

Contact your Roche service representative for any questions or information regarding **cobas** 6000 analyzer series training.

Contact customer service

Contact Roche service representative for further information regarding service agreement for the **cobas** 6000 analyzer series.

Ordering information

Replacement parts, consumable materials, reagents, calibrators and controls should be ordered from Roche service representative. When ordering, please use the Roche Diagnostics catalog number and reference name for each item. Contact your Roche service representative for the detailed ordering list.

Online Help system of the instrument

The user interface of the **cobas** 6000 instrument has a context-sensitive online help system to support you in operating the instrument.

Context-sensitive means that the help system displays information related to the current screen or software element. Therefore, the help system offers a quick and convenient way to find information.

The instrument software offers two help features:

- F1 Help
- Direct Help (tooltips)



F1 Help

The **F1 Help** feature displays information related to the current screen. Use this help feature if you require detailed information about this screen. Hypertext links guide you to additional information and procedures related to this screen.

For more detailed information, see *About F1 Help* on page B-13.



Direct Help

The **Direct Help** feature displays brief information related to a single software element, such as a button or field. Use this help feature if you only require a tooltip about an element.

For more detailed information, see *About Direct Help* on page B-20.

Videos in the Online Help system of the instrument

The Online Help system of the instrument is equipped with a number of video clips which show different maintenance tasks.

The video clips are only available if the instrument is in standby.

For information on the instrument status, see *Instrument status* on page B-233.

Conventions used in this manual

Visual cues are used to help locate and interpret information in this manual quickly. This section explains formatting conventions used in this manual.

Symbols The following symbols are used:

Symbol	Used for
►	Start of procedure
■	End of procedure
•	List item
	Cross-reference
	Tip
	Safety alert
	Electrical and electronic equipment marked with this symbol are covered by the European directive WEEE. The symbol denotes that the equipment must not be disposed of in the municipal waste system.

Abbreviations The following abbreviations are used:

Abbreviation	Definition
A	
Abs	Absorbance
ACN	Application code number
ANSI	American national standards institute
A.U.	Analytical unit (module short name and measuring cell, if applicable)
C	
c 501 (ISE)	ISE unit of the **c** 501 module
c 501 (P)	Photometric unit of the **c** 501 module
CLAS 2	Clinical laboratory automation system 2
COBI-CD	Compendium of background information
CSA	Canadian standards association
CSF	Cerebrospinal fluid
D	
DIL	Diluent
E	
e 601	**cobas e** 601 module for immunoassay analysis
EC	European community
ECL	Electrochemiluminescence
EN	European standard
F	
FBT	False bottom tube
H	
HbA1c	Hemoglobin A1c, glycosylated hemoglobin
HPE	High priority elecsys
I	
IEC	International electrical commission
IS	Internal standard (ISE module)
ISE	Ion selective electrode
IVD	In vitro diagnostic
K	
KCL	Potassium chloride, reference solution for the ISE unit of the **c** 501 module
kVA	Kilovolt-ampere. unit for expressing rating of AC electrical machinery.
L	
LDL	Lower detection limit *see* analytical sensitivity
LIS	Laboratory information system
LLD	Liquid level detection

Abbreviation	Definition
M	
MPA	MODULAR PRE-ANALYTICS
N	
n/a	Not applicable
NaCl	Sodium chloride
NG	Not good (calibration)
P	
PC/CC	ProCell M (ProCell) /CleanCell M (CleanCell)
PRE	Pretreatment reagent for immunoassays
PSM	Process system manager (software)
Q	
QC	Quality control
R	
RCM	Reaction calculation mode
REF	Reference solution for ISE module
RF	Radio frequency
R.M.	Result message
R.P. or R. pack	**cobas e** pack (reagent pack)
RRM	Rack reception mode
S	
SCCS	Special cell cleaner solution
SD	Standard deviation
SMS	Selective mode solution (Detergent for special washes of reagent probes)
STAT	Short turn-around time
Std	Standard, commonly used for calibrator
SVGA	Super video graphics adapter
T	
TPA	Tripropylamine
U	
UL	Underwriters laboratories Inc.
UPS	Uninterruptible power supply

System description A

1 General safety information A-3
2 Overview modules A-33
3 Control unit, cobas link and core unit A-43
4 c 501 module A-65
5 e 601 module A-93
6 Specifications A-109

General safety information

Before operating with the **cobas** 6000 analyzer series it is essential that the warnings, cautions, and safety requirements contained in this manual, as well as the explanation of safety labels on the system are read and understood by the user.

In this chapter *Chapter* 1

Safety classifications A-5
Safety precautions A-6
Operator qualification A-6
Commissioning and decommissioning A-6
Relocation and transportation A-7
Disposal A-7
Operating conditions A-7
Power interruption A-7
Electromagnetic devices A-8
Safe and proper use of the instrument A-8
Personal protection measures A-9
Biohazardous materials A-9
Electrical safety A-11
Mechanical safety A-12
Reagents and working solutions A-13
Skin contact A-13
Fire and burns A-13
Incorrect results A-13
Samples A-14
Reagents A-15
Instrument covers A-16
Others A-16
Sample loss A-17
Software and data security A-18
Unauthorized access A-18
Incorrect or corrupt data A-19
USB storage devices A-19
Computer viruses A-19
Third-party software A-19
Backup A-20

Instrument damage A-20
Moving parts A-20
Spillage A-20
Cleaning agents A-21
Excessive weight A-21
Safety labels of the system A-22
Front view A-24
Side view A-26
Top view A-27
Rear view A-29
Safety information for barcode readers A-30
Interlock function A-31
Disposal of the instrument A-32

Safety classifications

This section explains how precautionary information is presented in the manual.

The safety precautions and important user notes are classified according to ANSI Z535.6 Standards. Familiarize yourself with the following meanings and icons:



Safety alert

The safety alert symbol is used to alert you to potential physical injury hazards. Obey all safety messages that follow this symbol to avoid possible damage to the system, injury, or death.

These symbols and signal words are used for specific hazards:

⚠ WARNING

Warning

Indicates a hazardous situation which, if not avoided, could result in death or serious injury.

⚠ CAUTION

Caution

Indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.

NOTICE

Notice

Indicates a hazardous situation which, if not avoided, may result in damage to the instrument.

Important information which is not safety relevant, is indicated with the following icon:



Tip

Indicates additional information on correct use or useful tips.

Safety precautions



Pay attention to the following safety precautions!

If you ignore them you may be killed or suffer serious injuries.

Each precaution is important.

Keep in mind that the hazard warnings in this manual and on the instrument cannot cover every possible case, as it is impossible to predict and evaluate all circumstances beforehand.

Just following the given directions may, therefore, be inadequate for operation. Always be alert and use your common sense.

Operator qualification

As a user, you are required to be a licensed person according to your country's specific laws. You must have sound knowledge of relevant safety precaution guidelines and standards and of the information and procedures contained in the Operator´s Manual.

- Do not carry out operation and maintenance unless you have been trained by Roche Diagnostics to do so.
- Leave maintenance, installation, or service that is not described in the Operator´s Manual to the Roche service representative.
- Carefully follow the procedures specified in the Operator´s Manual for the operation and maintenance.
- Follow standard laboratory practices, especially when working with biohazardous material.

Commissioning and decommissioning

Only the Roche service representatives can perform commissioning.

For installation described in the Operator´s Manual (such as *Installing an application*), follow the installation instructions carefully.

Correct grounding of the power supply cord is essential for the correct function of the analyzer. The system can only be connected to a power supply source with the specified power supply cord and only by authorized personnel.

- Contact your Roche service representative for any changes to the power supply cord.

Relocation and transportation

Do not attempt to relocate or transport the instrument.

- Leave relocation and transportation to trained and authorized Roche Diagnostics personnel.

Disposal

For information about disposal of the instrument, see *Disposal of the instrument* on page A-32.

Operating conditions

Operation outside the specified ranges may lead to incorrect results or malfunction of the instrument.

- Never modify the instrument.
- Ensure that the instrument is operated in compliance with the system specifications.
- Use the instrument indoors only and avoid heat and humidity.
- Make sure that the instrument's ventilation openings remain unobstructed at all times.
- Perform maintenance according to the specified intervals to maintain the operating conditions of the instrument.
- Keep the Operator's Manual in a safe place to ensure that it is not damaged and remains available for use. This Operator's Manual must be easily accessible at all times.

Power interruption

A power failure or momentary drop in voltage may damage the instrument or lead to data loss.

- Operate only with an uninterruptible power supply (UPS).
- Ensure regular maintenance of the UPS.
- Perform regular backups of measurement results.
- Do not switch off the power while the PC accesses the hard disk or another storage medium.

Electromagnetic devices

Strong electromagnetic radiation (for example, unshielded intentional RF sources) can interfere with the proper operation and may lead to malfunction of the instrument and incorrect results.

Malfunction of the instrument and incorrect results due to interfering electromagnetic fields are possible.

This instrument has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case you may need to take measures to mitigate the interference.

- Evaluate the electromagnetic environment prior to operation of the device.
- Devices that emit electromagnetic waves may cause the instrument to malfunction. Do not operate this instrument in close proximity to sources of strong electromagnetic fields (for example, unshielded intentional RF sources).
- Do not operate the following devices in the same room where the instrument is installed:
 - Mobile phone
 - Transceiver
 - Cordless phone
 - Other electrical devices that generate electromagnetic fields

Safe and proper use of the instrument

For safe and proper use of the instrument, observe the following information.

Fatigue due to long hours of operation

Looking at the monitor screen over an extended period of time may lead to eye strain or body fatigue.

- Take a break for 10 to 15 minutes every hour to relax.
- Avoid spending more than 6 hours per day looking at the monitor screen.

Instrument unused for an extended period of time

If the instrument is not used for an extended period of time, the main circuit breaker must be switched to OFF.

- Remove, cap, and refrigerate any remaining reagents.
- For information on power off for a period up to 7 days and power on after this time, see the corresponding maintenance chapter.

 See *Extended Power OFF procedures* on page C-152.
- For information on power off for a period more than 7 days and power on after this time, call the Roche service representative.

 The necessary procedure is performed by your Roche service representative.

Approved parts

Use of non-approved parts or devices may result in malfunction of the instrument and incorrect results. It also may render the warranty null and void.

- Only use parts and devices approved by Roche Diagnostics.

Personal protection measures

This section describes how you can minimize your own risk during operation or maintenance.

Personal protective equipment

Wear appropriate protective equipment, including, but not limited to: safety glasses with side shields, fluid-resistant lab coat, and approved disposable gloves.

Wear a face shield if there is a chance of splash or splatter.

Handling of reagents and other working solutions

Reagents, calibrators, and controls must be handled, stored, and disposed of according to the instructions for use.

You are responsible for handling, storing, and disposing of samples and chemicals in accordance with the appropriate standards.

Biohazardous materials

Contact with samples containing material of human origin (for example, sample, waste) may result in infection. All materials and mechanical components (for example, reaction system, waste systems) associated with samples of human origin are potentially biohazardous.

- Follow standard laboratory practices, especially when working with biohazardous material.
- Keep the top and the front cover closed while the system is operating.
- Always switch the system to maintenance or shutdown mode before working with an opened cover (for example, cleaning or maintenance).
- Wear appropriate protective equipment.

 See *Personal protective equipment* on page A-9.
- If any biohazardous material is spilled, wipe it up immediately and apply disinfectant.
- If sample or liquid waste comes into contact with your skin, wash it off immediately with soap and water and apply a disinfectant. Consult a physician.

Sharp objects

Contact with probes may result in infection.

- When wiping probes, use several layers of gauze and wipe from the top down.
- Be careful to not puncture yourself.
- Wear appropriate protective equipment. Take extra care when working with protective gloves; these can easily be pierced or cut, which can lead to infection.

 See *Personal protective equipment* on page A-9.

Instrument mechanism

Aerosols could be formed inside the instrument, which are potentially hazardous. Contact with the sampling mechanism or other mechanisms may result in biohazardous contamination, causing personal injury and/or infection.

- Whenever possible, keep all of the instrument's covers closed and in place.
 - Do not open any cover while the instrument is operating or is performing maintenance.
 - Before starting any operation or maintenance, be sure to close and lock the top cover.
 - When working with an open top cover while the instrument is powered on (for example, for cleaning probes), always switch the system to **Maintenance** or **Shut Down** mode first. Observe all instructions given in the Operator´s Manual very carefully.
 - Allow only trained personnel access to the keys of the instrument covers.
 - Do not use the key for any purpose other than locking and unlocking the cover.
- During cleaning and maintenance, wear appropriate protective equipment. Take extra care when working with protective gloves; these can easily be pierced or cut, which can lead to infection.

 See *Personal protective equipment* on page A-9.
- Do not touch any parts of the instrument other than those specified. Keep away from moving parts during system operation.
- During operation and maintenance of the instrument, proceed according to the instructions.

Waste Contact with liquid waste may result in infection. All materials and mechanical components associated with the waste systems are potentially biohazardous.

- Wear appropriate protective equipment.
 See *Personal protective equipment* on page A-9.
- If any biohazardous material is spilled, wipe it up immediately and apply disinfectant.
- If liquid waste comes into contact with your skin, wash it off immediately with water and apply a disinfectant. Consult a physician.

Waste must be treated in accordance with the relevant laws and regulations. Any substances contained in reagents, calibrators, and quality controls, which are legally regulated for environmental protection, must be disposed of according to the relevant water discharge facility regulations. For the legal regulations on water discharge, please contact the reagent supplier.

Two kinds of liquid waste are discharged by the instrument:

- Concentrated liquid waste that contains highly concentrated reaction solution. Treat this waste as infectious waste. Dispose of this waste according to the appropriate local regulations.
- Dilute waste: A non-concentrated liquid waste diluted with rinsing water from cell wash or water from the incubator bath. When using NaOH-D for washing the reaction cells, alkaline concentration is 0.1 to 1.0 mmol/L in terms of sodium hydroxide equivalence. Dilute waste is discarded through tubes at the rear of the instrument.

When disposing of any waste generated by the instrument, do so according to the relevant laws and local regulations.

Liquid waste and replacement parts such as reaction cells and ISE electrodes have to be treated as infectious medical waste.

For information on disposal of the instrument, see *Disposal of the instrument* on page A-32.

Electrical safety

Removing the covers of electronic equipment can cause electric shock, as there are high voltage parts inside. In addition, opening the top cover of a photometric module (**c** 501) during operation can also cause electric shock.

- Do not attempt to work in any electronic compartment.
- Do not remove any covers from the instrument other than those specified in the Operator's Manual.
- Only authorized and qualified Roche Diagnostics personnel are authorized to perform an installation, service, and repair of the system.

Mechanical safety

Contact with the instrument mechanism could result in personal injury.

- Keep all covers closed and in place while the system is operating.
- Always switch the system to **Maintenance** or **Shut Down** mode first, before working with an open cover (for example, cleaning or maintenance).
- Only trained and authorized Roche Diagnostics personnel should have access to the keys for the protective covers of the system.
- Do not touch any parts of the system other than those specified. Keep away from moving parts during operation.
- Do not put your hands into the pathway of any moving parts during instrument operation.
- During operation and maintenance, proceed according to the instructions.

Fan Contact with the cooling fan during operation of the instrument may result in personal injury. There is a grille to protect the user from coming into contact with the moving fan.

- Do not insert your fingers into the opening of the ventilation grille.
- Shut down the instrument before cleaning. If you clean the fan while the instrument is not in shutdown mode, you risk personal injury.

Pierce pin A pierce pin for **cobas c** packs is located adjacent to the reagent probe rinse station. Contact with the pierce pin may result in personal injury.

- Do not touch the pierce pin and gripper during operation, cleaning, or maintenance.

Rack transfer mechanism The rack transfer mechanism can cause personal injury.

- Only load or unload racks when the green light on the rack loader is on.
- Do not insert your fingers or any objects into the rack loading/unloading area while the instrument is operating.
- Keep all covers closed and in place while the instrument is operating.

Cover Be careful when opening or closing a top cover. If you let go of the handle, the top cover may drop onto your fingers.

- Always keep a firm grip on the handle and do not let go when opening or closing a top cover.
- If a top cover does not stay open properly, please contact your local Roche service representative.

Reagents and working solutions

The **cobas** 6000 analyzer series uses reagent and working solutions, such as cleaners or diluents. Observe the following information on reagents and working solutions.

Skin contact

Direct contact with reagents, detergents, cleaning solutions, or other working solutions may cause skin irritation, inflammation, or burns.

- When handling reagents, exercise the precautions required for handling laboratory reagents.
- Wear appropriate protective equipment.
 See *Personal protective equipment* on page A-9.
- Observe the cautions given in the instructions for use.
- Observe the information given in the Material Safety Data Sheets (available for Roche Diagnostics reagents and cleaning solutions).
- Be careful when removing open reagent packs from the instrument. They may contain residues of reagents.
- If a reagent, detergent, or other working solution comes into contact with your skin, wash it off immediately with water and apply disinfectant. Consult a physician.

Fire and burns

Alcohol is a flammable substance.

- Keep all sources of ignition (for example, sparks, flames, or heat) away from the system when conducting maintenance or checks using alcohol.
- When using alcohol on or around the system, use no more than 20 mL at a time.

Incorrect results

An incorrect result may lead to an error in diagnosis, therefore posing danger to the patient.

- For proper use of the instrument, run QC tests and monitor the instrument during operation.
- Do not use reagents or consumables that have exceeded their expiration date, otherwise inaccurate data may be obtained.
- For diagnostic purposes: always assess the results in conjunction with the patient's medical history, clinical examination, and other findings.

Varying factors can influence the accuracy or precision of measured results. Pay particular attention to the following information on risks for incorrect results.

Samples

Any problem regarding the samples can cause incorrect results. Observe the following information on sample handling.

Sample mismatch

Be aware that in **non-barcode** mode there is a risk of sample mismatch. If samples are not placed in the proper positions, incorrect measurement results may occur.

- When operating in non-barcode mode, make sure to load the samples according to the **Requisition List** as provided by the instrument.
- Do not exchange or remove samples.
- Avoid empty positions within the racks. Do not place non-registered samples in any empty rack position.
- Do not insert any gray rack into the STAT port when operating in non-barcode mode because the predefined sequence of samples will be disrupted by the routine rack inserted through the STAT port.
- Do not reload an unloaded rack when working in non-barcode mode. In non-barcode mode, pink racks have to be used to reload samples.

Contamination

Insoluble contaminants in samples, bubbles, or film inside a sample container may cause blockage or pipetting volume shortage leading to compromised measurement accuracy.

- Make sure that samples contain no insoluble contaminants such as fibrin, dust, or bubbles.
- Make sure to prepare enough sample volume for measurement.

If foreign material falls inside the rack loading area, samples may get contaminated.

- Keep the cover of the rack loading area closed while the instrument is operating.
- Do not place anything on the cover of the rack loading area.

Evaporation of samples

Evaporation of samples may lead to incorrect results. For critical analytes in terms of on-board time, you must ensure a short turn-around time.

- After pipetting, do not leave sample, calibrators, or QC materials in a sample container for any length of time.

Foam or films

Foam, fibrin clots, or bubbles in sample types may cause pipetting volume shortage and lead to incorrect results.

- When loading samples, calibrators, and controls, make sure that they do not contain any foam, fibrin clots, or bubbles.
- Avoid the formation of foam in all sample types (specimens, calibrators, controls).

Carryover

Traces of analytes or reagents may be carried over from one test to the next.

- Take adequate measures to safeguard additional testing and to avoid potentially false results.

Sample volume

When using standard cups or micro cups, the correct sample cup type must be selected. Otherwise, the sample pipetting may be inaccurate and thus lead to inaccurate measurement results.

- Be sure to specify the sample cup type for standard cups and micro cups.

Reagents

Wrong reagent handling could cause incorrect results. Observe the following information on reagent handling.

Reagent volume

In case of an undetected loss of reagent, the instrument pipettes no reagent or the wrong volume of reagent. The system will calculate incorrect results.

- Do not reuse a reagent pack from which reagent was spilled.
- Reload a reagent pack only if you are sure the reagent volumes remained unchanged while it was not on the instrument.
- Do not use a single reagent pack for different instruments.

Reagents, auxiliary reagents, calibrators, and controls are sensitive regarding temperature and/or light, especially if the container is already open.

- Store reagents, calibrators, and controls always according to specified storage conditions.

When using **cobas c** pack MULTI, it must be filled with the exact filling volume specified in the instructions for use. Failure to do so may lead to incorrect results.

Additionally, an alarm (reagent short) may occur if the instrument detects low reagent volume.

- Ensure that the **cobas c** pack MULTI contains the correct filling volume. Refer to the instructions for use.

Expired reagents or mixing reagents

Results obtained using expired reagents are not reliable. Mixing new reagent and residues of old reagent may cause concentration changes or carryover, leading to incorrect results.

- Do not use expired reagents.
- Always store reagents according to the specified storage conditions.
- Do not top off old reagents with new reagents. When a bottle is empty, replace it with a new one.
- Do not leave reagents on the instrument for any length of time.

Foam or films

Foam on top or bubbles in reagents can cause pipetting volume shortage and lead to incorrect results.

- Avoid the formation of foam in all reagent types.
- Do not shake reagents.

Instrument covers

The instrument comprises various covers. Some covers are important for correct results. Observe the following information for instrument covers.

ISE measuring system

If the cover of the ISE measuring system is not reinstalled after maintenance, the temperature level or the noise level may be affected, leading to incorrect results.

- Only perform measurements if the cover of the ISE measuring system is closed.
- Before opening or closing the cover of the ISE measuring system, make sure the **c** 501 module is in standby or powered off.

***e** 601 module*

If the covers of the reagent compartment or the incubator are not reinstalled after maintenance, the temperature may become inaccurate, leading to incorrect results.

- Only perform measurements, when the covers are closed.

Others

Other causes can lead to incorrect results. Observe the following information on other causes.

Foam on ProCell/CleanCell

Foam on the surface of the **e** 601 ProCell/CleanCell reservoirs may also lead to incorrect results.

- Before start of analysis, check that no foam has accumulated on the surface of the **e** 601 ProCell/CleanCell reservoirs.
- Clean the ProCell/CleanCell reservoirs if foam has accumulated.

Incubator temperature

Measuring before the incubator has reached the correct temperature may lead to incorrect results and to incorrect results for the photometer check (maintenance (3) Photometer Check).

Measuring with open top cover or reagent disk cover may lead to abnormal temperature control, which may also cause incorrect results. Depending on the ambient temperature, it can take up to 30 minutes to reach the correct temperature after switching on the analyzer or after exchange of incubation water (maintenance item (5) Incubation Water Exchange).

- Before starting any measurement, check that the temperature of the incubator is within 37 ±0.1 °C (98.6 ±0.2 °F). Select each module on the **System Overview** screen to display the temperature of the incubator bath of the selected module.
- Be sure to close the covers before starting analysis.

Standard cups

Although non-Roche Diagnostics sample cups look similar, they may have a different inner geometry and may have been produced using non-specified materials. The liquid level detection and the level tracking are influenced by the inner geometry of the cup. Thus, air may be pipetted when non-Roche Diagnostics cups are used. This might not be detected under certain circumstances.

Sample cups from other vendors may cause inaccurate sample pipetting, which may lead to incorrect results.

- Use only cups certified by Roche Diagnostics.

Only the following original standard cups are certified by Roche Diagnostics:

- Hitachi standard cup
- **cobas** sample cup (catalog no. 10394246001)

Barcodes

Undetected barcode read errors may lead to sample mismatch and, therefore, to incorrect results.

- Use only barcodes with check digits.

Sample loss

In case of sample loss, there may not be enough sample left for measuring and, therefore, it is impossible to report results for diagnosis. This may lead to false diagnosis.

***Stop** (global button)*

Choosing **Stop** (global button) stops all sampling and sample processing, and results in process are lost.

- Before choosing **Stop** (global button), be sure sample processing has finished.

Interlock system

The interlock system of **c** 501 senses top cover opening and immediately stops the operation by cutting off the power. All pipetted samples are lost and must be reloaded.

- Before starting operation or maintenance, be sure to close and lock the top cover.
- Do not open the top cover during operation.

Software and data security

The control unit comprises a personal computer which controls the instrument, monitors the instrument functions, and provides and stores data (for example, test results, patient data, calibration, and control results, and so on). Therefore, there is a risk of unauthorized access and data loss due to malicious software and hacker attacks.

Unauthorized access

Portable storage media can be infected with and transmit computer malware, which may be used to gain unauthorized access to data or cause unwanted changes to software.

The instrument is not protected against malicious software and hacker attacks.

The users are responsible for IT security of their IT infrastructure and for protecting it against malicious software and hacker attacks. Failure to do so may result in data loss or render the instrument unusable.

Roche Diagnostics recommends the following precautions:

- Access to your data and the configuration should only be granted to authorized experts. All user interventions are logged in the system.
- Allow connection to authorized external devices only.
- Ensure that all external devices are protected by appropriate security software.
- Ensure that access to all external devices is protected by appropriate security equipment. Roche Diagnostics strongly recommends the use of a **cobas IT** firewall.
- Do not copy or install any software on the instrument unless it is part of the system software or you are instructed to do so by a Roche service representative.
- If additional software is required, contact your Roche service representative to ensure validation of the software in question.
- Do not use the USB ports to connect other storage devices unless you are instructed to do so by official user documentation or a Roche service representative.
- Exercise utmost care when using external storage devices such as USB flash drives, CDs, or DVDs. Do not use them on public or home computers.
- Before using a removable storage medium, it should be scanned by an antivirus program.
- Keep all external storage devices in a secure place and ensure that they can be accessed by authorized persons only.

Incorrect or corrupt data

The aim of passwords is to ensure that only authorized personnel have access to a system or information source. The combination of your unique user ID and password tells the system who you are and whether you are permitted access or not.

SECURE HANDLING OF YOUR PASSWORD IS CRUCIAL

- Always enter your password unobserved.
- Do not write down your password.
- Never note down the password in a contact form, in the address book, or in a file on the computer.
- Do not disclose your password to anyone.
- Roche Diagnostics will never ask you for your password.
- If you ever disclose your password to anyone, change it immediately afterwards.
- If you think your account has been compromised, then contact your Roche service representative.

USB storage devices

USB storage devices can be used for several kinds of data backups and restores. Wrong handling of a USB storage device may result in data loss or malfunction of the instrument.

- Insert or remove a USB storage device only when the instrument is in standby mode.
- At any one time only one USB storage device can be in use. Before inserting a USB storage device, check that no other USB storage device is inserted.
- Only remove USB storage devices after choosing **USB** (global button).
- Use only USB storage devices that are tested and installed by your local Roche service representative.

Computer viruses

If you detect an unexpected operation or program/data damage, the PC may be infected with a computer virus.

- Never use a program or storage medium that is suspected of containing a virus.
- If you think your PC is infected with a computer virus, call your local Roche service representative. Your local Roche service representative will disinfect your PC and will check the restoration.

Third-party software

Installation of any third-party software that is not approved by Roche Diagnostics may result in incorrect behavior of the instrument.

- Do not install any non-approved third-party software.
- Do not install a commercially available program on the control unit computer or change any PC settings.
- If additional software is required, contact your Roche service representative to ensure validation of the software in question.

Backup

Data may get lost due to aging of the hard disk or due to a hard disk failure because of electric power failure.

- Back up your data (measurement results and system parameters) at regular intervals.
- Use the backup function in a daily maintenance pipe to store relevant data on the hard disk.
- Make a backup copy if you have changed any system parameters.

Instrument damage

During operation, always check for any abnormal sound, water leakages, or other abnormal conditions. If a problem occurs, take suitable safety measures according to the condition and contact your Roche service representative.

Should one of the instrument circuit breakers or fuses blow, do not attempt to operate the instrument before contacting your Roche service representative.

Moving parts

Contact with moving parts may bend the probes or damage some other component. If the system detects a collision, an alarm will sound, stopping the operation immediately.

- Keep all covers closed and in place during operation.
- Do not touch any parts of the instrument other than those specified. Keep away from moving parts during operation.
- Only load or unload racks when the green status LEDs at the rack loading area are on.

Maintenance

If the instrument power is turned ON when performing manual maintenance, parts or tools may contact the instrument mechanisms and damage the instrument.

- Do not power on the instrument while performing manual maintenance.

Spillage

Any liquid spilled on the instrument may result in malfunction or damage of the instrument.

- Do not place samples, reagents, or any other liquid on the surface of the instrument.
- When removing and replacing the reaction cells, be careful not to spill water from the incubator bath.
- If liquid does spill on the instrument, wipe it up immediately and apply disinfectant. Wear protective equipment.

See *Personal protective equipment* on page A-9.

Cleaning agents

Some cleaning agents may damage the instrument. Observe the following instructions to avoid instrument damage during cleaning.

Alcohol or bleach

Alcohol or bleach may damage the surfaces of the instrument.

- Do not use alcohol or bleach to clean the instrument surfaces.

Acid or alkaline solutions

The pre-wash mixer, the incubator, and the AssayCup vortex mixer are made of aluminum. Acid solution or an alkaline solution degrades the metal.

- Do not use an acid solution or an alkaline solution to clean these parts of the instrument.
- Use deionized water to clean these parts of the instrument.

Excessive weight

Excessive weight on the instrument may damage the instrument.

***c** 501 module*

Excessive weight on the cassette table of the **c** 501 module may lead to damage.

- Do not place anything other than **cobas c** packs on the table.
- Maximum load of the table is 2 kg.

***e** 601 module*

Excessive weight on the magazine drawer of the **e** 601 module may lead to damage.

- Do not open the front door of the magazine drawer and do not pull out the magazine drawer when the indicator lamp is off or blinking.
- Pull out the magazine drawer gently and do not lean on the magazine drawer.

Safety labels of the system

Warning labels have been placed on the analyzer to draw your attention to areas of potential hazards. The labels and their definitions are listed below according to their location on the instrument.

The safety labels on the system comply with the following standards: ANSI Z535, IEC 61010, IEC 60417, or ISO 7000.

If the labels are damaged, they must be replaced by your local Roche service representative. For replacement labels, contact your local Roche service representative.



Spillage warning

This label indicates the instrument may be damaged if a spillage occurs within the vicinity of this label. Do not place liquids in this area.



Protective equipment warning

This label indicates protective goggles and gloves should be worn when working within the vicinity of this label as there is a danger of coming into contact with corrosive material.



Warning

This label indicates there is a danger of hazardous situations within the vicinity of this label, which may result in death or serious injury. Refer to the Operator's Manual for safety operation.



Biohazard warning

This label indicates there are potential biohazards within the vicinity of this label. Follow standard laboratory practices for working with biohazardous materials.



Electrical warning

This label indicates there is a danger of coming into contact with electrical components when gaining access to parts of the system marked with this label.



Mechanical parts warning

This label indicates there is a danger of coming into contact with moving mechanical parts within the vicinity of this label.



Sharp object warning

This label indicates there is a danger of coming into contact with sharp objects which may result in injuries.



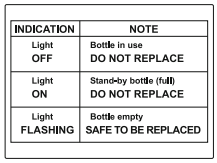
Hot surface warning

This label indicates the area within the vicinity of this label may be hot. Do not touch this area as you may be burned.



Maximum weight

This label indicates the maximum weight. Do not place anything heavier than the specified weight on the label.



INDICATION	NOTE
Light OFF	Bottle in use DO NOT REPLACE
Light ON	Stand-by bottle (full) DO NOT REPLACE
Light FLASHING	Bottle empty SAFE TO BE REPLACED

Green button light states

This label indicates the meaning of the status of the green button lights. DO NOT perform an action unless the correct state is indicated.

The following sections describe the meaning of the safety labels on the instrument in a short form.

For more information about the safety labels on the instrument, see:
Front view on page A-24
Side view on page A-26
Top view on page A-27
Rear view on page A-29
Safety information for barcode readers on page A-30

In addition to *safety labels* on the instrument there are *safety notes* in the corresponding parts of the Operator's Manual and Online Help.

For more information, see:
Part *Operation* on page B-1
Part *Maintenance* on page C-1

These safety notes give more detailed information about potentially hazardous situations in the context of all kinds of working procedures.

When working with the analyzer be sure to observe both safety labels on the instrument and safety notes in the Operator's Manual and Online Help.

Front view

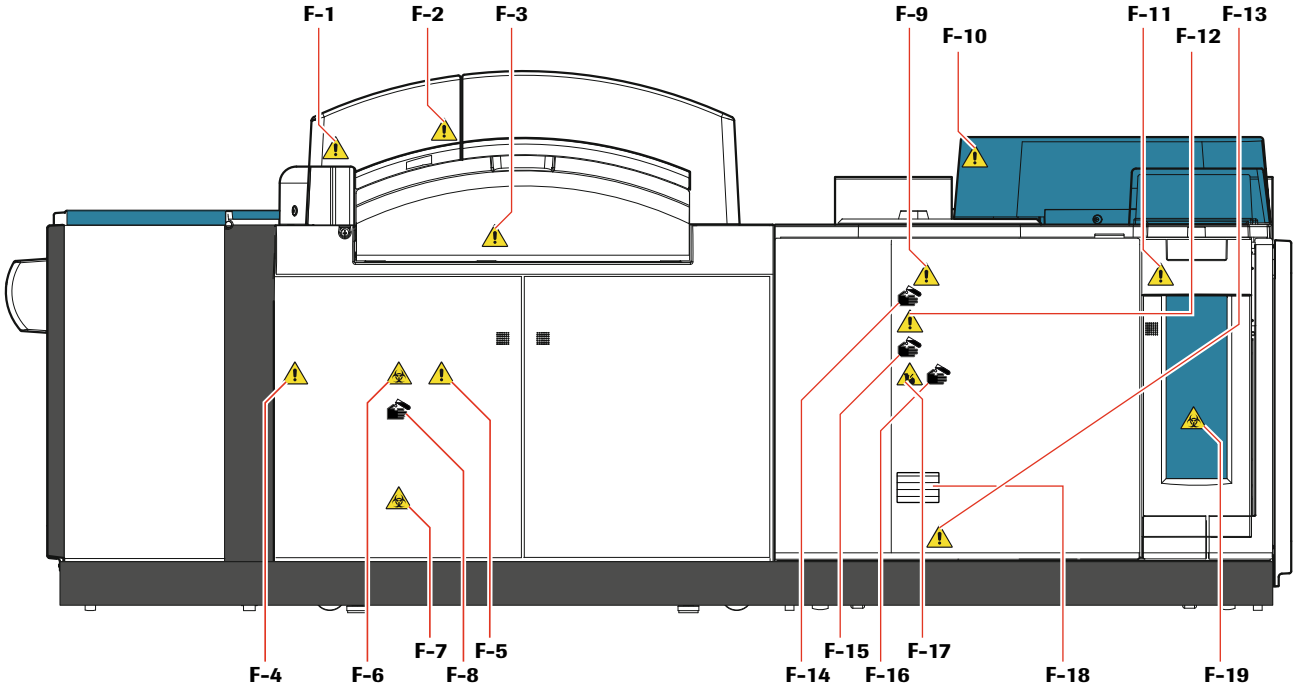
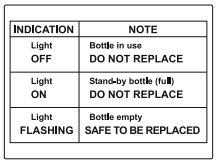


Figure A-1 Front view of the analyzer

F-1		**Attention to interlock!**
F-2		**Caution against contact with pierce pin!**
F-3		**Caution against contact with mechanism!**
F-4		**Caution against pinch by syringe!**
F-5		**Caution against false result due to loose tube connector!**
F-6		**Caution against infection due to contact with sipper syringe!**
F-7		**Caution against infection due to contact with waste from the vacuum tank!**
F-8		**Caution against irritation by detergent and/or reagent!**
F-9		**Caution against pinch by syringe**

F-10		**Caution against injury and infection due to contact with mechanical parts!**
F-11		**Attention to handling the magazine drawer!**
F-12		**Attention to auxiliary reagent setting!**
F-13		**Attention to auxiliary reagent misplacement!**
F-14		**Caution against irritation by detergent and/or reagent!**
F-15		**Caution against irritation by detergent and/or reagent!**
F-16		**Caution against irritation by detergent and/or reagent!**
F-17		**Caution against injury by contact with needle!**
F-18		**Attention to the status of the green lights!**
F-19		**Caution against infection due to contact with tips and AssayCups!**

Side view

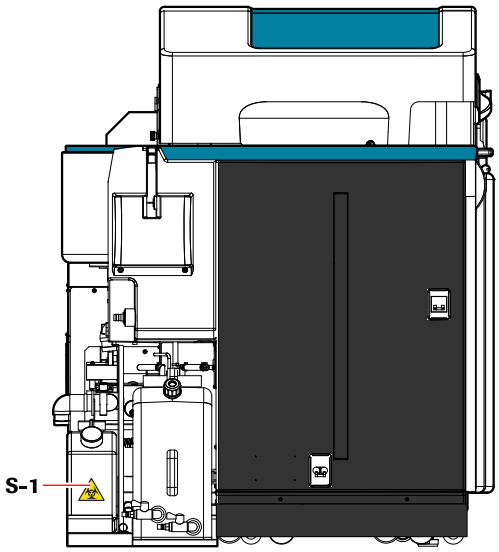


Figure A-2 Right side of the analyzer

S-1		**Caution against infection due to contact with waste solution in waste solution tank!**

Top view

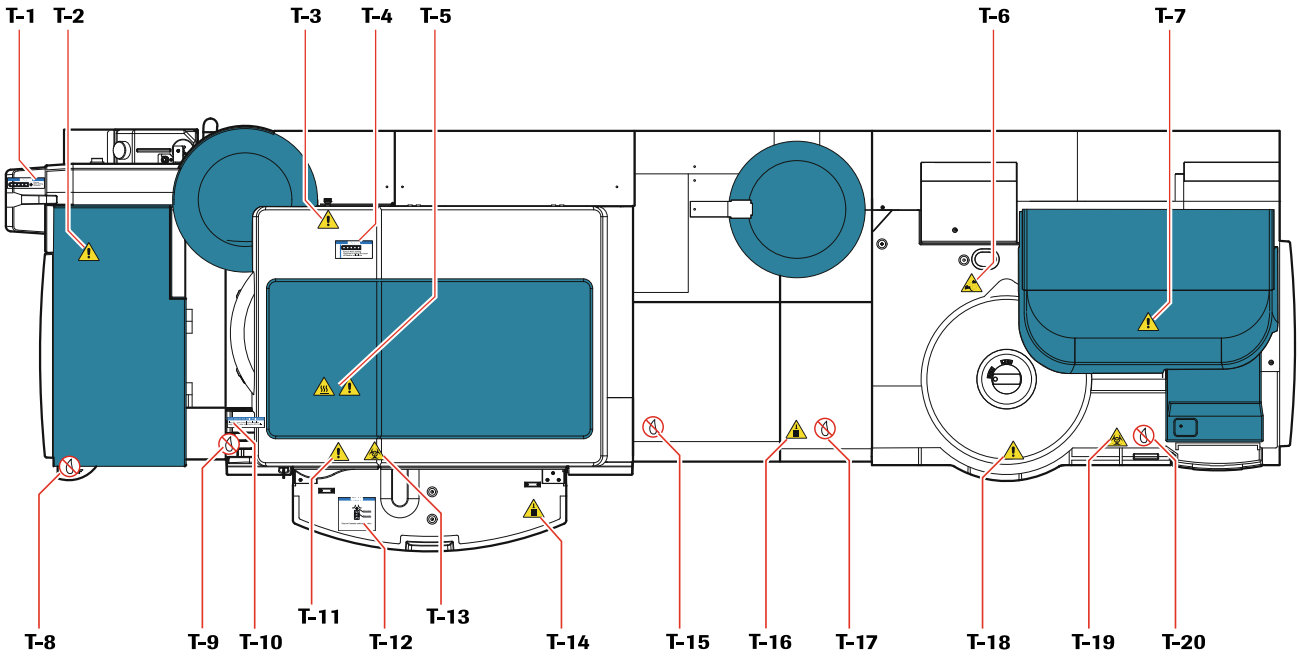
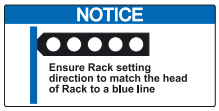
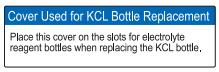
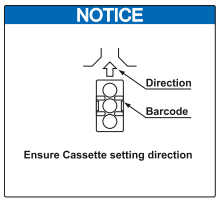


Figure A-3 Top view of the analyzer

T-1		**Attention to rack direction when loading racks at the STAT port!**
T-2		**Attention to sampler cover!**
T-3		**Caution against pinch by rotor mechanism!**
T-4		**Attention to rack direction when loading racks at the backup operation port!**
T-5		**Caution against burn at photometer lamp replacement!**
T-6		**Caution against entanglement by reagent disk!**
T-7		**Attention during incubator maintenance!**
T-8		**Instrument damage by water!**
T-9		**Instrument damage by water!**

Safety labels of the system

T-10		**Reminder to use cover for KCL bottle replacement**
T-11		**Attention when opening or closing ISE cover!**
T-12		**Attention to cassette direction when loading cassettes!**
T-13		**Caution against infection due to contact with parts of the ISE compartment!**
T-14		**Attention to cassette table maximum weight!**
T-15		**Instrument damage by water!**
T-16		**Attention to cassette table maximum weight!**
T-17		**Instrument damage by water!**
T-18		**Attention when opening or closing reagent disk cover!**
T-19		**Caution against infection due to contact with mechanism!**
T-20		**Instrument damage by water!**

Rear view

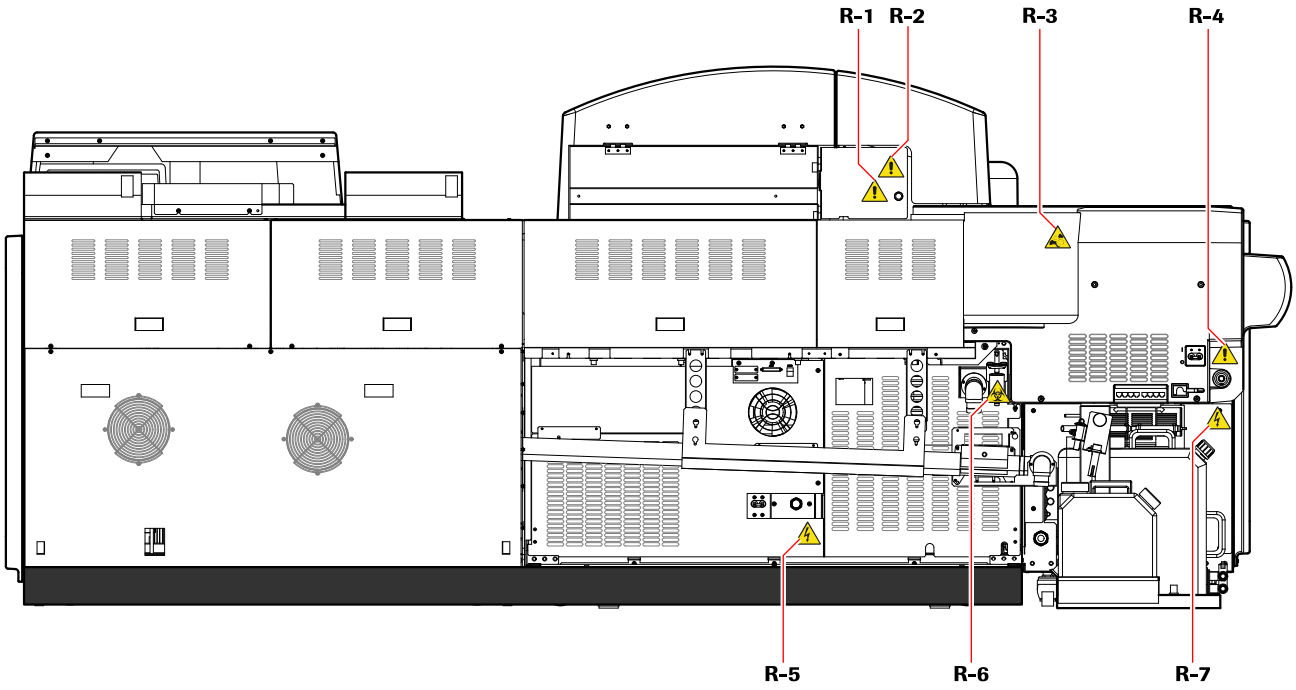


Figure A-4 Rear view of the analyzer

R-1		**Caution against contact with mechanism!**
R-2		**Attention to cover with a key!**
R-3		**Caution against entanglement by rack rotor!**
R-4		**Attention during water filter maintenance!**
R-5		**Attention to electric shock at the back side of the instrument!**
R-6		**Caution against infection due to contact with ISE waste solution!**
R-7		**Attention to electric shock at the lower part of the rack sampler unit!**

Safety information for barcode readers

⚠ WARNING

Loss of sight caused by intense light of barcode readers

The intense light of a laser or LED barcode reader may severely damage your eyes or result in hazardous radiation exposure.

- Do not stare into the beam of a LED barcode reader.
- Do not remove covers from barcode readers.
- Do not perform any maintenance actions on barcode readers. If problems concerning the barcode readers occur, contact your local Roche service representative.

The following figure shows the position of the barcode readers and the directions of the LED apertures used by the **cobas** 6000 analyzer series:

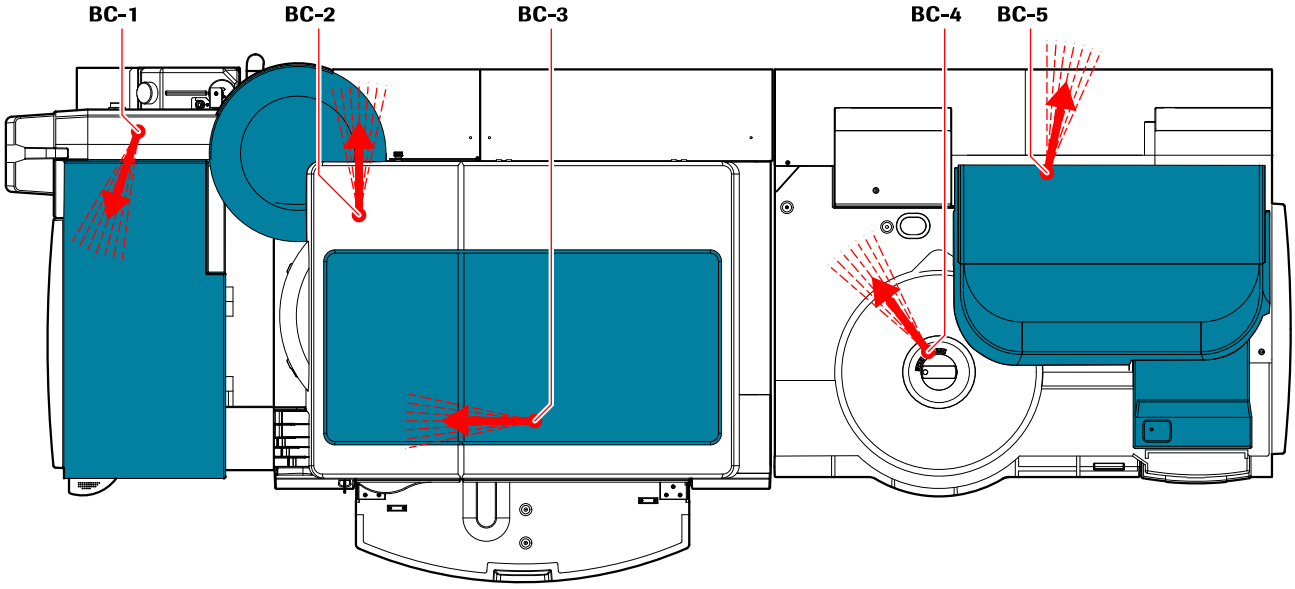


Figure A-5 Top view of the analyzer - localization of barcode readers

The following table gives technical information about the intensity of the barcode readers:

Barcode no.	Module	Barcode reader used for	Maximum LED radiation output power	LED class /Classified standard
BC-1	**cu** 150	Rack ID and sample ID	10 µW	Class 1 LED product
BC-2	**c** 501	Rack ID and sample ID	10 µW	IEC 60825-1, +A2:2001
BC-3		Reagent	10 µW	
BC-4	**e** 601	Reagent	102.92 µW	
BC-5		Rack ID	10 µW	

Table A-1 Barcode readers of the **cobas** 6000 analyzer series

Interlock function

The top cover of the **c** 501 module is equipped with an interlock function to protect the operator from being injured by moving parts. If the top cover of the **c** 501 module is opened, the interlock function cuts the power to and stops all moving parts. An alarm is triggered.

If you want to continue operation or perform a maintenance item, you have to put the instrument back to standby.

To put the instrument back to standby, see *Interlock function: Reset after stop* on page B-235.



A Top cover

Figure A-6 **c** 501 module

Disposal of the instrument

The instrument must be treated as potentially biohazardous waste. Decontamination (that is, a combination of processes, including cleaning, disinfection and/or sterilization) is required before reuse, recycling, or disposal of the instrument.

Dispose of the instrument according to the appropriate local regulations. Before disposing of the instrument, contact your Roche service representative.



Disposal of control unit components

Components of your control unit (such as the computer, monitor, keyboard) that are marked with this symbol are covered by the European Directive on *Waste Electrical and Electronic Equipment* (WEEE, 2002/96/EC).

These items must be disposed of through designated collection facilities appointed by government or local authorities.

For more information about disposal of your old product, please contact your city office, waste disposal service, or your Roche service representative.

Constraint:

It is left to the responsible laboratory organization to determine whether control unit components are contaminated or not. If contaminated, treat in the same way as the instrument.

Overview modules

This chapter provides an overview of all modules of the **cobas** 6000 analyzer series. A description of possible configuration is provided, as well as system specifications and environmental conditions.

In this chapter *Chapter* 2

Overview A-35
Modules of the cobas 6000 analyzer series A-36
Control unit and cobas link A-37
Core unit A-38
c 501 module A-39
Photometric unit A-39
ISE unit A-40
e 601 module A-40
Second rotor module A-41

Overview

The **cobas** 6000 analyzer series is a fully automated, software-controlled system for clinical chemistry and immunoassay analysis. It is designed for both quantitative and qualitative in vitro determinations using a large variety of tests for analysis. It is ready to use 24 hours per day. The **cobas** 6000 analyzer series:

- is fully automated
- is modular
- is computerized
- uses serum/plasma, urine, CSF, supernatant and whole blood sample types
- performs in vitro quantitative and qualitative tests on a wide range of analytes
- performs photometric assays and ion-selective electrode measurements on **c** 501 modules as well as electrochemiluminescence assays on **e** 601 modules

Modules of the cobas 6000 analyzer series

The **cobas** 6000 analyzer series comprises of a control unit, core unit **cu** 150 and the following hardware units, which can be combined in various combinations:

- **c** 501 module
- **e** 601 module



Figure A-7 The **cobas** 6000 analyzer series

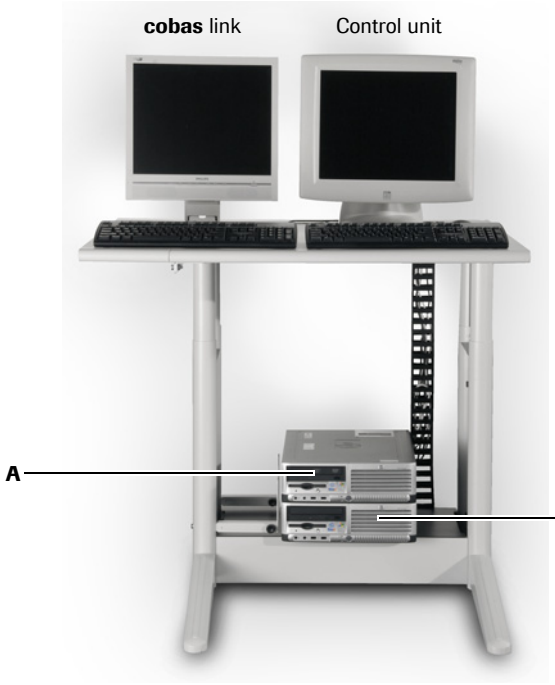
The modularity of the system allows for up to seven combinations of the above hardware units and thus provides tailored solutions for all medium workload requirements:

Clinical chemistry	< c > < c c >	Up to 2000 tests/h (photometric and ISE) for a <cc> system Up to 1000 test/h for a single <c> system Up to 60 **cobas c** packs per **c** 501 module
ECL technology	< e > < e e >	Up to 340 tests/h for a <ee> system Up to 170 test/h for a single <e> system Up to 25 **cobas e** packs per **e** 601 module
Hybrid combinations	< c e > < c c e > < c e e >	Up to 2170 tests/h Up to 145 reagent packs

Control unit and cobas link

The control unit uses a graphical user interface to control all instrument functions. The **cobas** link PC is used as the gateway for retrieving and distributing information—such as important notes and test- and lot-specific analyzer settings—from Roche TeleService-Net to **cobas** analyzers.

The following figure shows the control unit together with the **cobas** link PC:



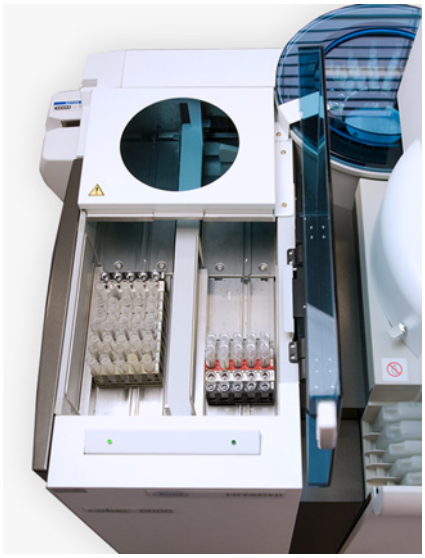
A **cobas** link PC **B** Control unit computer

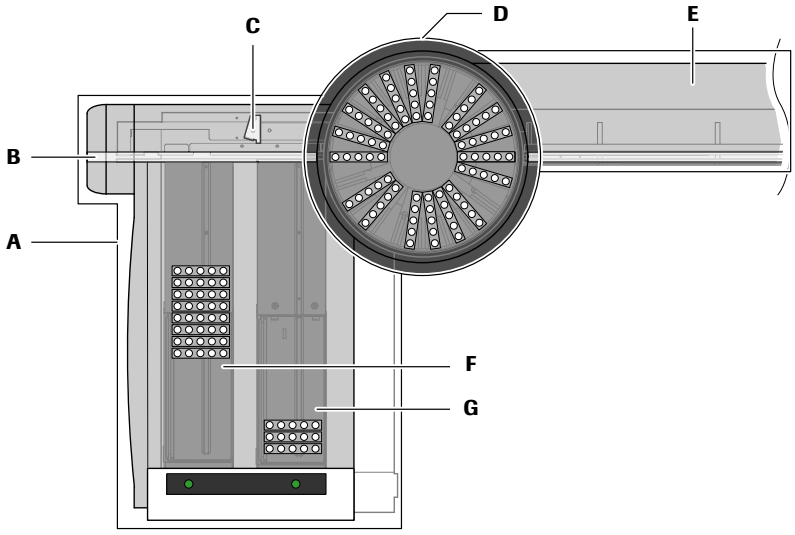
Figure A-8 Control unit and **cobas** link PC

Any component of the control unit is subject to change without prior notice.

Core unit

The core unit comprises several components that manage the transport of samples to each assigned analytical module.





A Rack sampler unit
B STAT port
C Barcode reader
D Rack rotor
E Conveyor line (depending on system configuration)
F Rack loader
G Rack unloader

Figure A-9 Core unit **cu** 150

Other core module components (installed into the rack sampler unit) are:

- Water supply
- System interface port
- Power switches
- Main circuit breaker

c 501 module

The **c** 501 module comprises a photometric unit and an ISE unit (for ion-selective electrode [ISE] determinations).



Figure A-10 **c** 501 module

Photometric unit

The photometric unit provides the analyzer with a flexible photometric method of assaying up to 600 in vitro tests per hour on a wide range of analytes. The following are the main components of the **c** 501 module:

- Sampling system
- Reagent system
- Reaction disk system

Sampling system The sampling system is composed of a sample pipetter (consisting of a pipetter arm and the sample probe), a sample syringe, and a rinse station for internal and external rinsing of the sample probe.

Reagent system The reagent system is composed of a refrigerated reagent compartment consisting of two storage rings for reagent cassettes, and a reagent pipetting system with two rinse stations for internal and external rinsing of the reagent probes.

Another integral part of the reagent system is the cassette management system, which provides a fully automated management of reagent cassettes—from the point of loading of new cassettes all the way to the disposal of empty cassettes.

Reaction disk system The reaction disk system is composed of a reaction disk, immersed in an incubator bath, three ultrasonic mixing units, a photometric measuring system, and a cell rinse unit for cleaning the reaction cells once test measurement is complete.

ISE unit

Moreover, the **c** 501 module has an integrated ISE unit, which provides the analyzer with a potentiometric method for assaying sodium, potassium and chloride samples. The ISE unit can process up to 200 samples per hour. The following are the main components of the ISE unit:

- ISE measuring compartment with measuring cartridges for Cl^-, K^+, Na^+ and Reference cartridge
- ISE pipetter
- ISE sipper
- IS bath
- ISE reagent compartment

e 601 module

The **e** 601 module is an immunoassay analyzer with a throughput of up to 170 tests per hour. The **cobas** 6000 analyzer series can be configured with up to two **e** 601 modules.



Figure A-11 **e** 601 module

The following are the main components of the **e** 601 module:

- Reagent area
- Measuring area
- Consumables area
- Pre-wash area

Reagent area The reagent area comprises the left side of the analyzer and consists of a reagent disk, a barcode reader, a cap open/close mechanism, a microbead mixer, a reagent probe and two rinse stations.

Measuring area The measuring area is in the middle of the analyzer and consists of an incubator, a sample probe, two sipper probes, two sipper rinse stations, and the two measuring cells.

Pre-wash area The Pre-wash station, located in the middle at the back of the analytical module, carries out a pre-wash step to remove special contents of serum from the reaction solution before measuring if required by the assay protocol. The Pre-wash station consists of a Pre-wash gripper, Pre-wash sipper, Pre-wash dispenser, rinse station, separation stations, and the vortex mixing station.

Consumables area The consumables area is on the right side of the **e** 601 and consists of the gripper, the mixing station, the AssayTip station, the magazine lifter trays, two solid waste containers, the magazine waste compartment, and the auxiliary reagents and cleaning solutions.

Second rotor module

Only **cobas** 6000 analyzer series with a specific configuration have a second rotor module.



Figure A-12 Second rotor module

The second rotor module routes racks from the core unit to the second and third analyzer modules and back to the first rack rotor. The second rack rotor also acts as rack buffer for the automatic rerun function.

Systems with the following configurations have a second rotor module:

- <c 501> <c 501>
- <c 501> <c 501> <e 601>
- <c 501> <e 601> <e 601>

The second rotor module is always placed between the first and the second analyzer module.

Control unit, cobas link and core unit

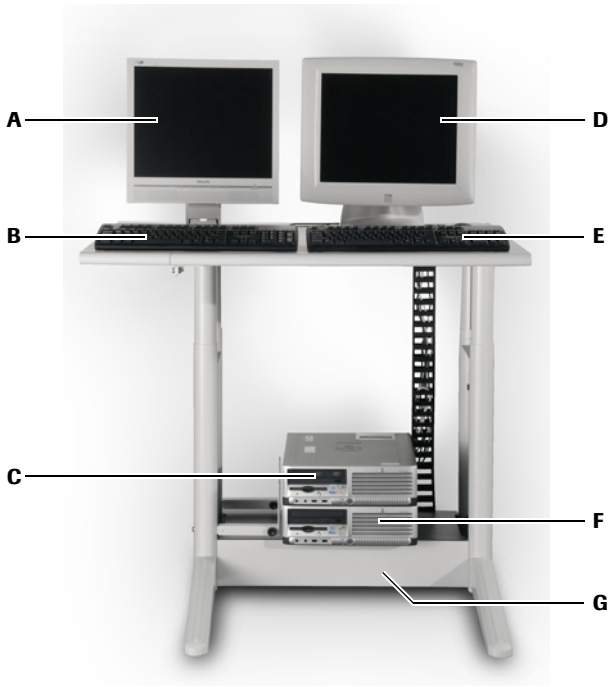
This chapter provides a detailed description of the control unit, the **cobas** link platform, and the core unit. The description of the core unit includes the rack sampler unit, the rotor, and the conveyor line, as well as line movements within these components. The sample containers, sample racks, and the rack identification are also described in this chapter.

In this chapter *Chapter* 3

Control unit A-45
Control unit computer A-45
Touchscreen Monitor A-46
Keyboard A-46
Mouse A-46
Printer A-46
cobas link A-47
Overview A-47
Main functions A-49
Working with cobas link functions A-50
Using e-barcodes via download A-50
Using the backup function A-51
Using e-package inserts A-51
Core unit cu 150 A-52
Rack sampler unit A-53
Rack loader/unloader A-54
STAT port A-55
Barcode reader / cup sensor A-55
Power switches A-56
System interface port A-56
Water supply A-57
Rack rotor A-58
Trays, racks, tubes, and cups A-59
Rack trays A-59
Sample racks A-59
Sample containers A-61
Correct placement of sample tubes on a rack A-62

Control unit

The control unit uses a graphical user interface to control all instrument functions. The following figure shows the control unit together with the **cobas** link PC:



A Monitor **cobas** link
B Keyboard/Mouse **cobas** link
C **cobas** link PC
D Touchscreen Monitor
E Keyboard/Mouse
F Control unit computer
G Ergonomic PC stand

Figure A-13 Control unit and **cobas** link PC

Do not place the computer, touchscreen or any data storage media in the vicinity of electric or magnetic fields, since this may led to damage and/or data loss.

Control unit computer

The control unit computer monitors the system functions, and operation modes for all modules.

- A hard disk drive is used to store the operating system, the analyzer software, the Online Help system and data, for example patient data, calibration data, QC data and system parameters.
- A 31/2 inch floppy disk drive is available for reading and writing parameters and other information for backup purposes.
- A CD or a DVD drive is available for loading software updates.

Touchscreen Monitor

The system uses a 17" SVGA with color monitor touchscreen adapter to:

- Display information
- Navigate through the software
- Initiate instrument functions

To use a touchscreen, touch what you want to request or change directly on the screen. Most of the items within the software can be accessed using the touchscreen. Touch the item desired (for example, menu bar, list box, text box, button, etc.) to complete your task. For example, to display the **Data Review** screen in the **Workplace** menu, touch **Workplace**, then the **Data Review** tab.

When touching the screen, be sure to “tap” not “press”. The tap must be of short duration. When touching the screen, you can use your finger or a pointing device.

Selecting Items

To select a consecutive range of items in a list, press <Shift> and touch the first item in the range. While continuing to press <Shift>, touch the last item in the range. All items, including the first and last items touched in the range, are highlighted. You may also touch the first item in the list and drag your finger to the last item in the list.

To select multiple, nonconsecutive items, press <Ctrl>, then touch the desired items.

Keyboard

A 101-key enhanced keyboard is used to navigate through the software and to enter information.

Most items that can be accessed via the touchscreen can also be accessed via the keyboard.

For more information, see *Shortcut Keys* on page B-11.

Mouse

A mouse is available to navigate through the software.

The mouse can be used to select items on the screen and to place the cursor at an insertion point in a text box. To select an item using the mouse, move the mouse over the item and then click.

Printer

The system uses a graphics-capable printer. Patient results can be printed in report format (long) or in monitor format (short). The printer can be ordered as an optional accessory.

See *Report Format* on page B-306.

cobas link

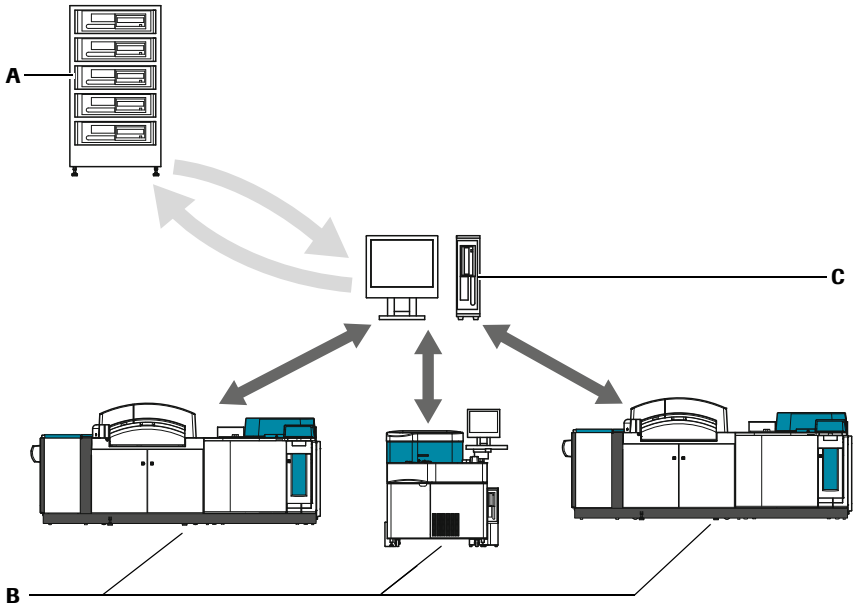
This section explains the principles of the **cobas** link platform and gives an introduction to working with **cobas** link.

Overview

***cobas** link platform*

The **cobas** link platform is the gateway for retrieving and distributing information from the Roche remote service infrastructure to **cobas** analyzers in the laboratory (Figure A-14). Information such as instructions for use, value sheets, important notes, as well as test-specific and lot-specific analyzer settings are made available through **cobas** link

cobas link is an integral and mandatory part of the **cobas** modular platform analyzers.



A Remote service infrastructure
B **cobas** analyzers
C **cobas** link PC

Figure A-14 **cobas** link platform

A number of applications and other information, for example about controls and calibrators, are available on the **cobas** link, which automates manual tasks, improving efficiency and reducing errors.

No patient names or patient IDs are transferred to or stored within the remote service infrastructure.

Remote service infrastructure

Remote service infrastructure is the technical infrastructure which provides the **cobas** analyzers and operators with important product information from Roche Diagnostics. Remote service infrastructure offers several applications to manage and display data and information gathered from remotely connected instruments which are uploaded by **cobas** link located in the laboratory systems.

***cobas** link PC*

A dedicated desktop computer consisting of monitor, keyboard, mouse, and printer located in the customer laboratory, which has been configured to act as a gateway between Roche Diagnostics systems and the internet. As well as providing a communication link, the **cobas** link PC also stores data and documentation for assay processing.

***cobas** e-library*

cobas e-library runs on the **cobas** link platform. **cobas** e-library receives data, from the remote service infrastructure, about assay parameters as well as labeling information for the applications, controls, and calibrators used on **cobas** analyzers. This data is then made available to the connected analyzers, ensuring that they always have the current data when it is required. Laboratory staff can also view and print this data, when needed, through **cobas** e-library.

cobas e-library is updated daily by an automatic download if it is connected to a network. New catalogue numbers, calibrator lots, and control lots are displayed by default.



Regular updates

It is important to update **cobas** e-library regularly to ensure you receive all important information as it becomes available.

There is a separate Operator's Manual for the **cobas** e-library available.

For information on working with the **cobas** e-library, refer to the **cobas** e-library Operator's Manual.

If your laboratory does not have an online connection to remote service infrastructure, the **cobas** e-library data is provided on a CD, distributed by your local Roche service representative.

For information on working with CDs, refer to the **cobas** e-library Operator's Manual.

Main functions

From the operator's point of view the main functions of **cobas** link are:

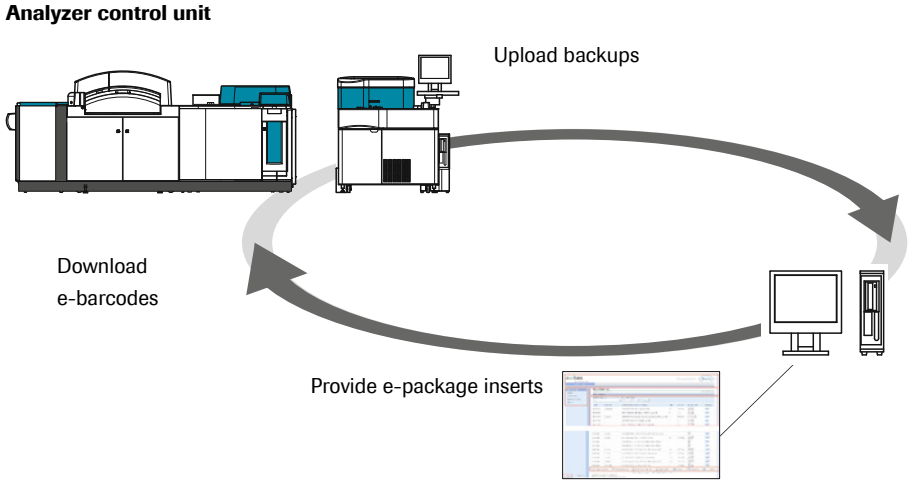


Figure A-15 **cobas** link - main functions

e-package inserts (e-PI)

The **cobas** e-library stores many documents (e-package inserts) which can be viewed, printed, and saved:

- Instructions for use for the applications
- Value sheets of controls and calibrators
- Important notes (for example, reassigned control values)
- Announcements from Roche service representatives (for example, customer letter)

See *Using e-package inserts* on page A-51.

e-barcodes (e-BC)

Providing e-barcodes like application parameters to be downloaded from **cobas** link to the analyzer by the operator. e-BCs are readable by the instrument only.

See *Using e-barcodes via download* on page A-50.

e-reference documents

e-reference documents provide current product information.

Screen sharing

Screen sharing is a function to support the instrument and the user.

Backup function

Providing the possibility of data backup for the **cobas** 6000 analyzer series.

See *Using the backup function* on page A-51.

Working with cobas link functions

This section explains the working principles of the main **cobas** link functions.

Using e-barcodes via download

The operator downloads the required e-barcodes from the **cobas** link PC to the analyzer.

The following types of e-barcodes are available:

- Application data
- Calibrator data
- Control data

The following figure gives an overview of the installation process.

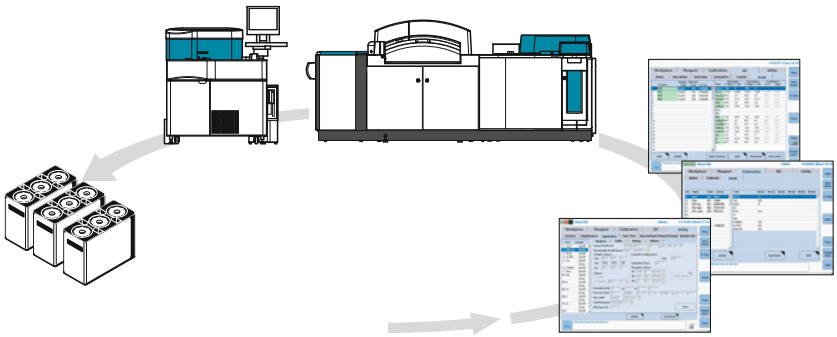


Figure A-16 Installation process of a new **cobas** application

If the data of a particular application (application parameters, calibrator data, and control data) is not available on the analyzer, it has to be downloaded from **cobas** link.

For more information, see *Installing an application* on page B-252.

A detailed description for installing new applications, calibrators, and controls is given in the corresponding chapters.

For a more detailed description see:
To download application parameters from cobas link on page B-255
To download calibrator data from cobas link on page B-186
To download control data from cobas link on page B-222

Using the backup function

Instrument and process related data can be stored on the hard disk of the **cobas** link PC for recovery. In order to initiate this backup function it is necessary to include the **cobas** link upload function (*Smart. Com Essential information upload*) in a maintenance pipe that is carried out daily (for example, as part of the *Power ON* pipe).

This item can only be performed in a maintenance pipe.

For more information, see:
Defining and editing maintenance pipes on page C-11
Recommended maintenance pipes on page C-32
Smart. Com Essential information upload on page C-42

Perform daily backups to preserve the operational availability of the analyzer!

Include the **cobas** link upload function (*Smart. Com Essential information upload*) into a maintenance pipe that is executed daily. If a hard disk error on the control unit occurs, the last backup can be restored from the **cobas** link PC by a Roche service representative.

Using e-package inserts

You can view, print, and save e-package inserts from the **cobas** e-library.

The e-package inserts (e-PI) consists of the following electronic documents:

- Instructions for use
- Value sheets of calibrators and controls
- Important notes (for example, reassigned control values)
- Announcements from Roche service representatives (for example, customer letter)

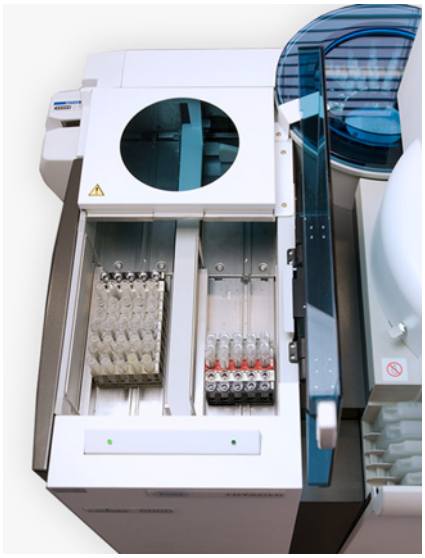
Check your cobas e-library daily to obtain important information

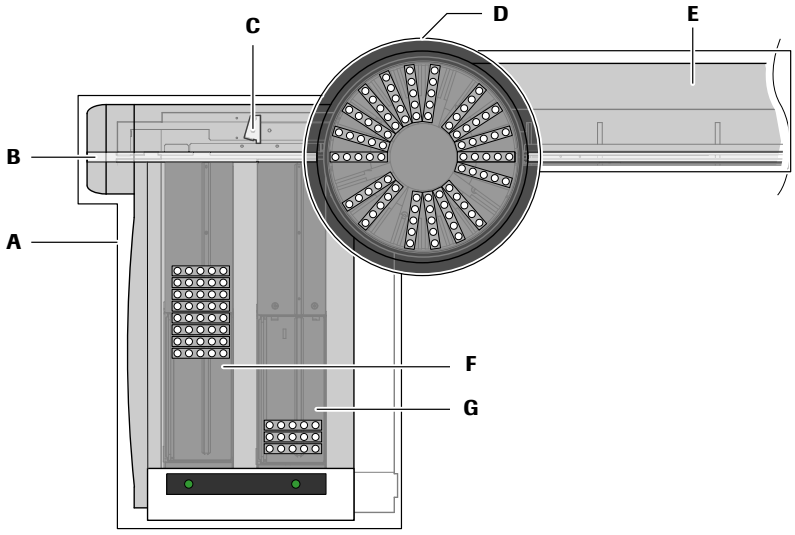
It is important to check your **cobas** e-library daily (**New Entries**) because important information that is necessary for analysis—like reassigned control values—is announced through the **cobas** e-library.

For information on working with the **cobas** e-library, refer to the **cobas** e-library Operator's Manual.

Core unit cu 150

The core unit comprises several components that manage the conveyance of samples to each assigned analytical module. Therefore, the actual composition depends on the current module configuration of the analyzer. The core unit comprises at least the rack sampler unit and one rack rotor as main components. Conveyor line(s) and second rack rotor are possible extensions.





A Rack sampler unit
B STAT port
C Barcode reader
D Rack rotor
E Conveyor line (depending on system configuration)
F Rack loader
G Rack unloader

Figure A-17 Core unit **cu** 150

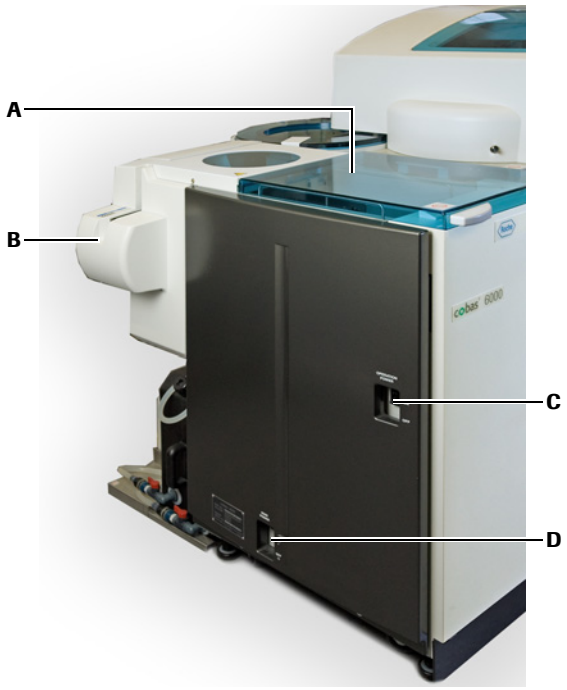
The following are main components of the core unit:

- Rack sampler unit
- Rack rotor(s)
- (Conveyor line[s])

Other core unit components (installed into the rack sampler unit) are:

- Rack loader/unloader
- STAT port
- Barcode reader (for racks and samples)
- Water supply
- System interface port
- Power switches
- Main circuit breaker

Rack sampler unit



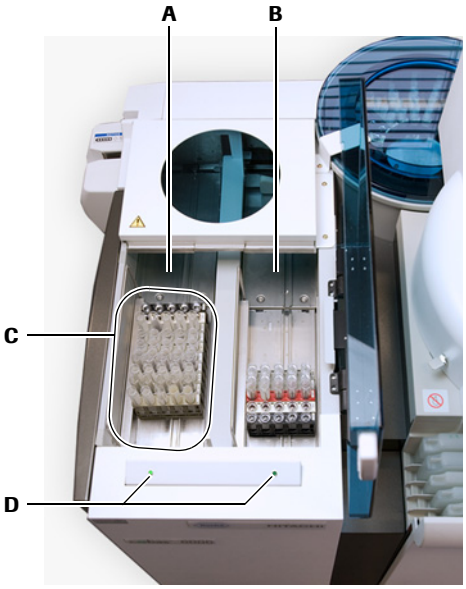
A Rack loader/unloader
B STAT port
C Operation power switch
D Main circuit breaker

Figure A-18 Rack sampler unit

All central control and supply functions of the core unit are installed into the rack sampler unit.

The following subsections describe the rack loader/unloader, STAT port, barcode reader, and power switches. Then, we turn to the rear of the rack sampler unit and discuss the system interface and the water supply.

Rack loader/unloader



A Rack loader
B Rack unloader
C Rack tray (with racks)
D Green LED

Figure A-19 Rack loader/unloader

Viewed from above, the rack sampler unit features two lanes where sample racks (or rack trays with sample racks) are to be inserted; the left lane is the rack loader, the right lane is the rack unloader. Both the loader and the unloader have a capacity of 150 samples, corresponding to 30 racks each. The racks are supplied on rack trays.

Make sure the rack barcode label is on the right side when placing a rack on a tray. The barcode label can be read only when racks are supplied in correct orientation.

The rack loader is designed for continuous loading. That is, the operator can load new samples while others are still being processed. When the analyzer is in operation, the green LEDs indicate when a rack tray can be exchanged. That is, when new sample racks can be inserted or when a rack tray can be removed from the unloader.

When the analyzer is in operation, rack loading proceeds automatically. When the analyzer is in standby, rack loading initiates after the operator starts the run.

Rack loading

The rack loader automatically pushes the sample racks forward. One after another, the racks are pushed onto a feeder, which transports each rack into the rack rotor. When transporting the racks into the rack rotor, a barcode reader scans the barcode and a sensor checks the height of each sample container. From the rack rotor, the racks move to the analytical module where their samples are analyzed.

After analysis, the racks move from the analytical module via the rack rotor to the unloader. The unloader collects the processed sample racks up to a maximum of 30 racks.

STAT port



Figure A-20 STAT port

Use the STAT port to send any racks directly onto the rack rotor, bypassing all racks on the trays of the rack loader. A rack loaded through the STAT port will be processed with higher priority than other racks in rack rotor.

To locate the STAT port on the rack sampler unit, see Figure A-18 on page A-53.

Make sure the rack barcode label is on the right side when inserting a rack into the STAT port. The barcode label can be read only when racks are supplied in correct orientation.

Any rack can be put into the processing track at any time by using the STAT port. However, when operating in non-barcode mode, routine (gray) racks must not be put into the processing track by using the STAT position! Doing so would disrupt the predefined sample sequence and lead to sample mismatch for all subsequent samples.

For information on the different types of racks, see *Sample racks* on page A-59.

Barcode reader / cup sensor

When racks are loaded onto the analyzer, either via rack loader or via STAT port, they pass by a barcode reader and a height sensor before they enter the rack rotor. This barcode reader performs the following tasks:

- Scans rack barcode of each rack
- Detects if there is a sample in each of the five rack positions
- Detects the type of sample tube or cup present
- Scans barcodes on each sample within a rack

The height sensor cannot distinguish between sample cups and microcups.

Power switches

There are two types of power switches: Superordinate power switches and power switches for each module.

Superordinate power switches (on the left of the rack sampler unit):

- Operation power switch
- Main circuit breaker

👁 To locate the superordinate power switches, see Figure A-18 on page A-53.

Power switches for each module (at the rear of each module):

- Module power switch for the rack sampler unit
- Module power switch for the **c** 501 module and the **e** 601 module

Power switch	Dependent components
Operation power switch	Whole analyzer except for cooling unit
Main circuit breaker	Whole analyzer including the cooling unit
Module power switch for the rack sampler unit	Rack sampler unit (including rack rotor)
Module power switch for the **c** 501 module and the **e** 601 module	**c** 501 module, **e** 601 module

Table A-2 Power switches and dependent components

System interface port

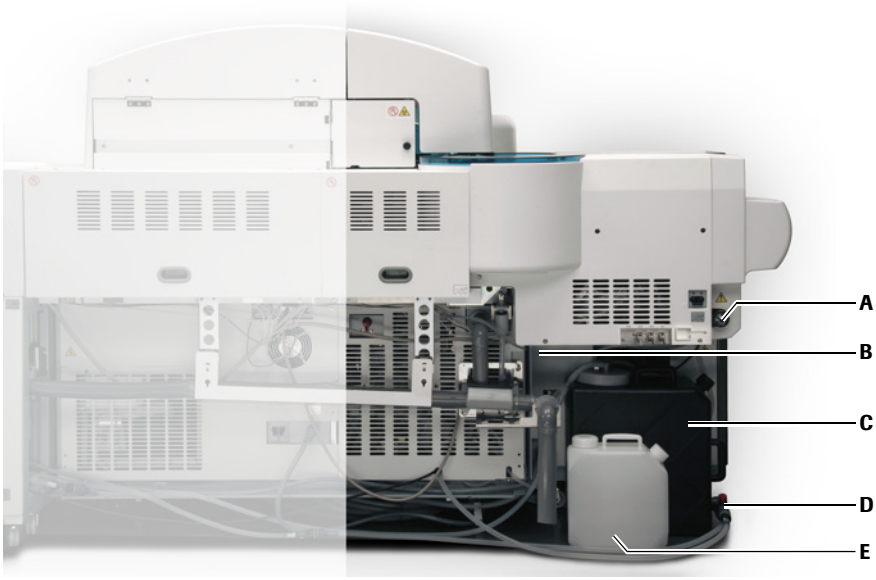
The following components take part in the data communication within the analyzer and its network environment:

- Rack sampler unit
- Connected analytical modules
- **cobas** link
- Host computer

There are two devices to accomplish the data communication: A serial port for bidirectional communication with the Host computer and a hub for network connections. The hub is located on the PC stand.

👁 For technical information about the serial interface, see *System interface* on page A-113.

Water supply



A Fitting with inlet filter
B System interface port
C Water tank
D Tap for water tank
E High concentration waste container

Figure A-21 Water supply

The deionized water supply system consists of the water tank, located behind the rack sampler unit, connecting tubing, and a series of electronic valves. Water is automatically added to the water tank when necessary. Water from this source is supplied directly to the cell rinse unit, to the rinse stations, and to the incubator bath.

For more information about water consumption and specifications, see *Water requirements* on page A-112.

Rack rotor



Figure A-22 Rack rotor

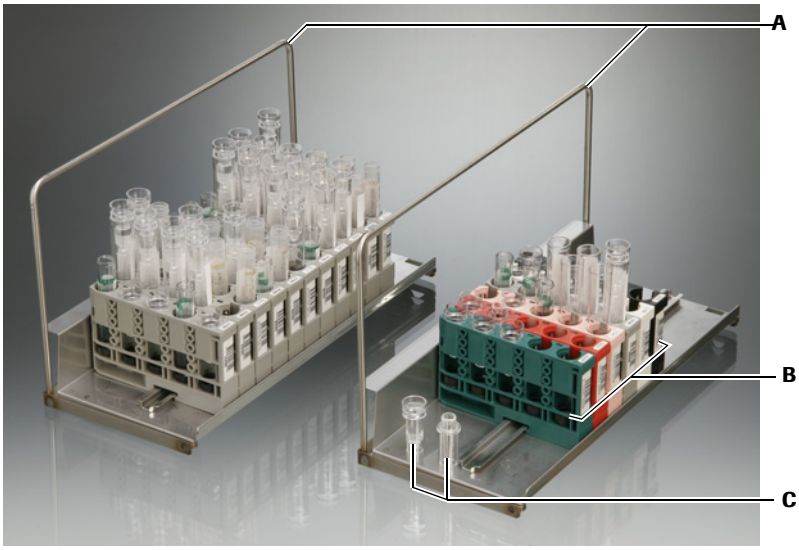
The rack rotor is located at the rear between the rack sampler unit and the analytical module (**c** 501 or **e** 601, depending on system configuration). The rotor has 20 positions for sample racks. It receives sample racks from the rack loader, passes them on to the **c** 501 module or the conveyor line, receives sample racks from the **c** 501 module after pipetting or from the conveyor line, and passes them on to the unloader.

In addition, the rack rotor can hold special racks (auto QC) readily available and reserve special positions for STAT racks. Any of the 20 positions is freely definable for STAT or auto QC.

If your **cobas** 6000 analyzer is equipped with two **c** 501 modules or with one **c** 501 and two **e** 601 modules, then a module with a second rack rotor is placed between the first and the second analyzer module.

Trays, racks, tubes, and cups

This section describes the different containers and components used to transport samples.



A Rack Trays

B Sample racks with different tubes, cups and cup on tube

C Standard cup, micro cup

Figure A-23 Trays, racks, tubes, and cups

Samples are supplied to the analyzer in sample tubes or cups. These sample containers are inserted in sample racks, which are placed on rack trays.

Rack trays

Rack trays are used to transport sample racks to and from the rack loader/unloader. Each tray has a capacity of 15 racks. This corresponds to a number of 75 samples that can be loaded onto the analyzer with one tray.

Sample racks

The analyzer distinguishes the following categories of samples:

- Patient samples
 - Routine samples
 - STAT samples
 - Rerun samples
- Calibrators
- Quality controls.

Each sample category has its own type of sample rack. Each sample rack holds a maximum of five samples. To load sample racks, they are either inserted at the STAT port or placed on a tray and the tray is placed into the rack loader.

Make sure the rack barcode label is on the right side, when inserting a rack into the STAT port or when placing a rack into the rack loader. The barcode label can be read only when racks are supplied in the correct orientation.



Figure A-24 Sample racks

Sample racks are color-coded and equipped with a barcode label and a label with a unique rack number. Each rack is identified and registered when its barcode label is scanned by the barcode reader of the rack sampler unit.

The following table explains the different types of racks, their color codes and numbers:

Rack type	Rack color	Display in software	Label on rack
Routine rack	Gray	N00001-N03999	001-3999
STAT rack	Red	E00001-E00999	S001-S999
Rerun rack[(a)]	Pink	R00001-R00999	R001-R999
Calibrator rack	Black	S00001-S00999	C001-C999
QC rack	White	C00001-C00999	Q001-Q999
Wash rack	Green	W00999	W999

Table A-3 Rack types

(a) Rerun racks are used for manual reruns in non-barcode mode only.

The table shows that each type of sample rack has its specific range of rack numbers. The software allows subdividing the range of rack numbers of routine, rerun, and STAT racks according to sample types (such as Ser/Pl, Urine, CSF…). This assignment of sample types to rack numbers is displayed in the **Rack Assignment** area on **Utility** > **System**.

The rack labels displayed in the software differ from those printed on the racks.

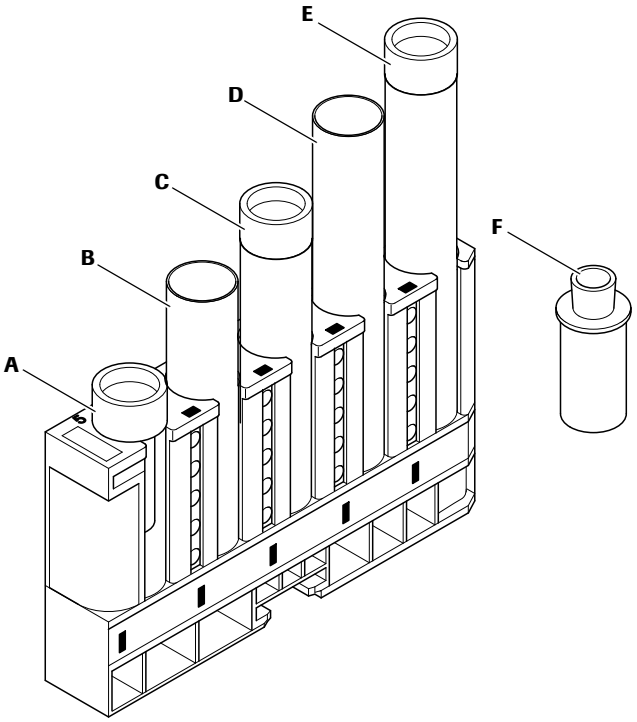
Sample containers

There are three general kinds of sample containers: Sample tubes, sample cups, and calibrator or control vials.

Sample tubes and cups

Sample tubes are 13 mm or 16 mm in diameter and 75 mm or 100 mm in length. Sample cups (both standard and micro cups) can be inserted into 16-millimeter sample tubes (*cup on tube*) or they can be used without tubes.

For sample container specifications, see *Sample cups and tubes* on page A-116.



A Sample cup on rack
B 16 mm x 75 mm tube
C Sample cup on 16 mm x 75 mm tube
D 16 mm x 100 mm tube
E Sample cup on 16 mm x 100 mm tube
F Micro cup

Figure A-25 Sample container heights

Restrictions for the use of micro cups

When the end of sample probe touches the inner wall of a micro cup this may result in improper sample aspiration.

- Do not use micro cups on **e** 601 modules.
- Do not use micro cups for calibrators and controls.

Non-standard tubes

Sample tubes with the following dimensions can also be used:

- Length between 73 mm and 102 mm
- Outer diameter between 12 mm and 16 mm

Non-standard tubes and false bottom tubes can be used for patient samples and controls.

Please contact your Roche service representative for more information about the use of non-standard tubes and other sample containers.

Sample identification

When operating in barcode mode, each sample's barcode label is scanned by the barcode reader of the rack sampler unit. The sample barcode label provides the sample ID, which is used for sample identification and test selection purposes.

For label dimensions and placement specifications, see *Barcode types* on page A-114.

The combination of the sample ID and the rack identification number provides tracking for the system. To track samples by means of the software, select **Sample Tracking** from the **System Overview** screen.

When operating in non-barcode mode, samples are identified by a sequence number, the rack number, and their position in the sample rack. This assignment has to be done on the **Workplace** > **Test Selection** screen.

Correct placement of sample tubes on a rack

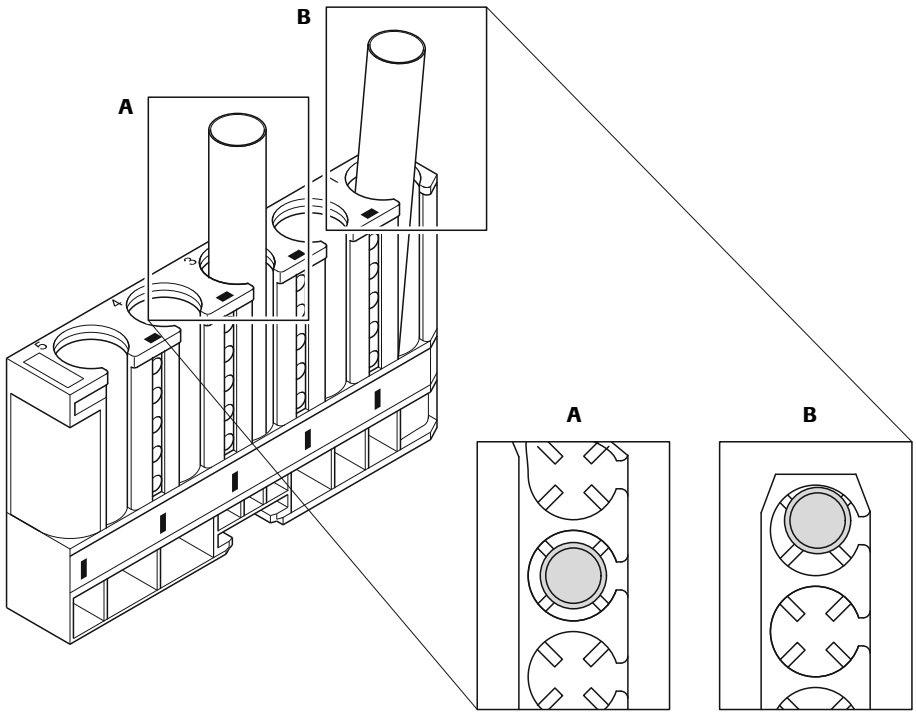
Take special care to place sample tubes correctly on the rack. This is especially important for 13 mm tubes, which are narrower and more likely to tilt if placed incorrectly. If the tubes are not correctly placed in an upright position on the rack, the sample probe may attempt to aspirate air or not enough sample if the probe hits the side of the tube, causing errors and incorrect results.

Samples, racks, and sample types

Make sure to put the samples in the correct assigned rack e.g. urine in urine rack as defined on **Utility** > **System** > **Rack Assignment**.

*Correct placement **without** Cup-Adapters*

The following figure illustrates correct and incorrect placement of a sample tube on the rack. The tube should be placed correctly in the rack so that the tube is vertical.

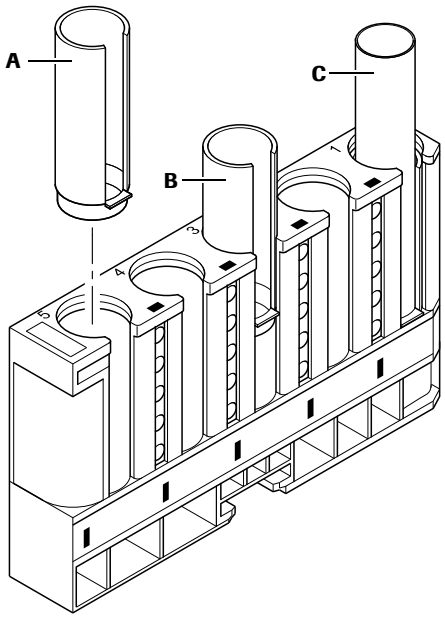


A Correctly placed tube **B** Incorrectly placed tube

Figure A-26 Correct placement of a sample tube on the rack

*Correct placement **with** Cup-Adapters*

To improve the alignment of 13 mm tubes on the rack, Roche recommends that the Roche Cup-Adapters are used. Cup-Adapters are placed as an insert to the standard rack, as shown in the following figure.



A Roche Cup-Adapter
B Insert Cup-Adapter into rack
C 13 mm tube inserted in a Cup-Adapter

Figure A-27 Fitting a Cup-Adapter to a 5-position standard rack

The Roche Cup-Adapters should be used only for the sample tubes specified for use with the **cobas** 6000 analyzer. Tubes with an outer diameter greater than 13 mm should not be used in combination with Cup-Adapters, because the barcode label might be damaged.

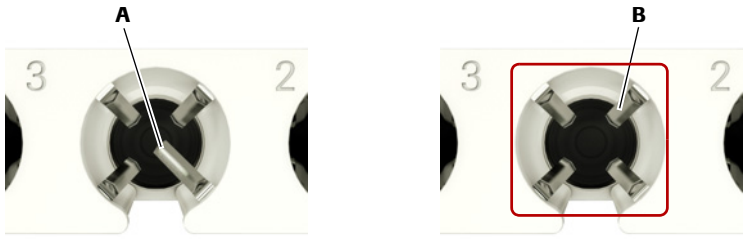
Roche Cup-Adapter cannot be removed

Be aware that a Roche Cup-Adapter cannot be removed if inserted on a position of a rack.

Conditions for 13 mm tubes without cup adapters

You can omit the cup adapters for 13 mm sample tubes if the following preconditions are fulfilled:

- The **cobas** 6000 is connected with a **cobas**© 8100 automated workflow series. In this clinical laboratory automation system, a gripper arm places the sample tubes into the racks.
- The sample probes are precisely adjusted in horizontal and vertical direction on all modules. The adjustment must be performed by your Roche Service representative.
- All spring clips are symmetrically bent in the used racks so that the sample tubes are held vertically.



A Incorrect - spring clips are not symmetric **B** Correct - spring clips are symmetric

Table A-4 Spring clips in racks

c 501 module

This chapter provides a detailed description of the **c** 501 module, its hardware components and technical specifications.

In this chapter *Chapter* 4

Overview A-67
System characteristics A-67
Components of the c 501 module A-68
Sampling area components A-70
Sample pipetter A-70
Sample probe rinse station A-71
Sample syringe A-71
Reagent area components A-72
Reagent storage compartment A-72
Reagent pipetting system A-73
Reagent pipetters A-73
Reagent syringes A-74
Reagent probe rinse stations A-74
Cassette management system A-75
Cassette loading port A-75
Cassette preparation station A-76
Piercer and Gripper A-76
Cassette disposal A-76
Reaction disk area components A-77
Reaction disk A-78
Ultrasonic mixers A-78
Incubator bath A-78
Photometer A-79
Cell rinse unit A-80
Flow of photometric analysis A-82
Main functions on the reaction disk area A-82
Main steps of photometric analysis A-83
Reaction monitoring A-85

Behind the front doors A-86
Auxiliary reagents and cleaning solutions A-87
Vacuum system A-87
Rear view A-88
ISE area components A-89
ISE pipetting system A-90
Internal standard bath A-90
ISE sipper mechanism A-90
ISE measuring system A-91
ISE rinse station A-91
ISE reagent compartment A-91
Flow of an ISE analysis A-92

Overview

The **c** 501 module is a fully automated, discreet, computerized analyzer for in vitro tests on a wide range of analytes. It is designed to use serum/plasma, urine, CSF, supernatant and whole blood sample types. The **c** 501 module performs photometric assays as well as ion-selective electrode (ISE) determinations. The throughput is up to 1000 tests per hour for a combination of photometric and ISE tests.



Figure A-28 **c** 501 module

This chapter describes the **c** 501 module. The rack rotor and rack sampler unit belong to the core unit.

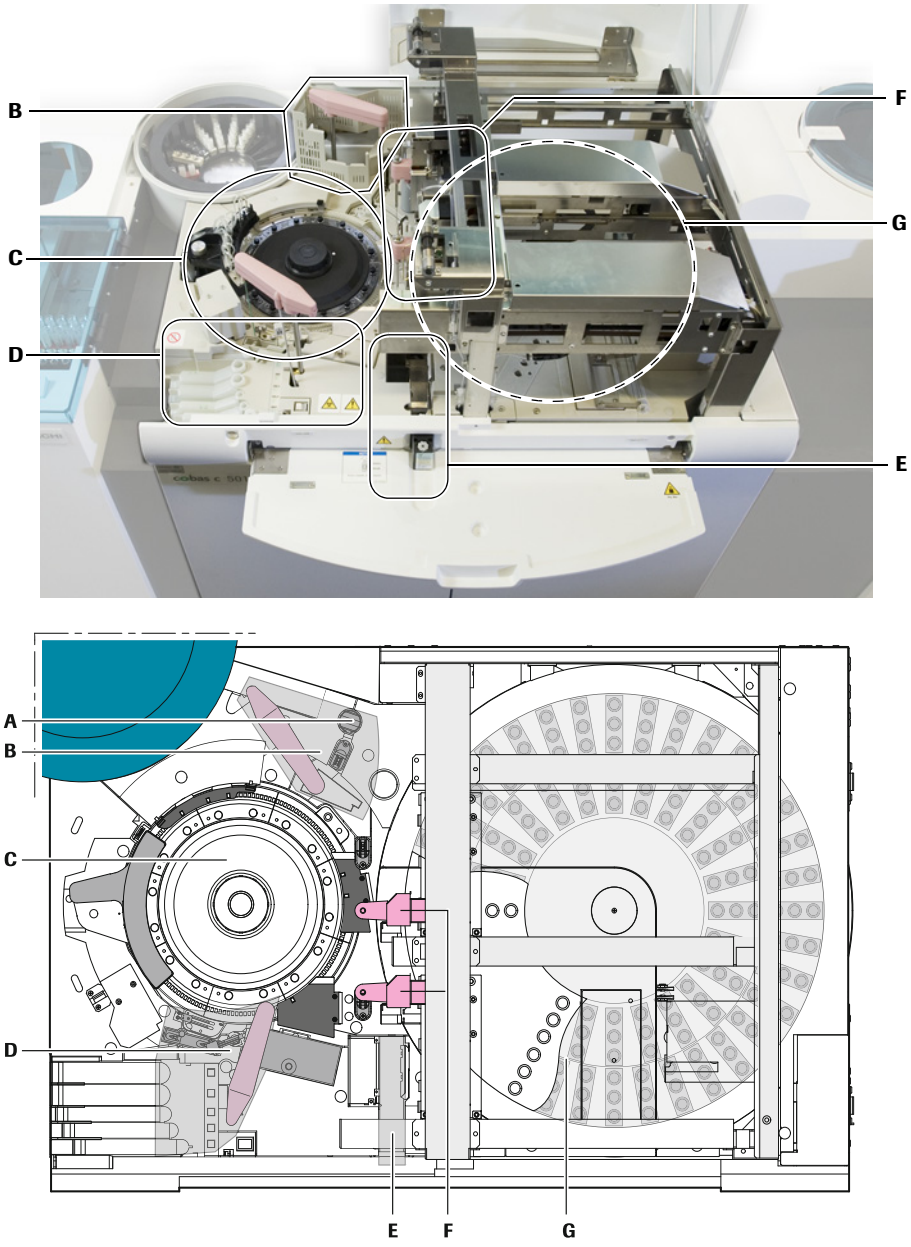
For a detailed description of the core unit, see Chapter 3 *Control unit, cobas link and core unit*.

System characteristics

- 131 on board pre-programmable applications
- STAT sample processing within less than 2 min.
- Automatic reagent cassette loading and unloading
- Automated maintenance functions
- Automatic rerun capability
- Automatic calibration notification
- Automatic sample dilution capabilities
- Non-contact ultrasonic mixing
- Reduced water consumption
- HbA1c whole blood support
- Backup solution for core unit

Components of the c 501 module

The **c** 501 module contains an ISE unit and a photometric unit. Figure A-29 sketches the different areas from a top-view perspective:



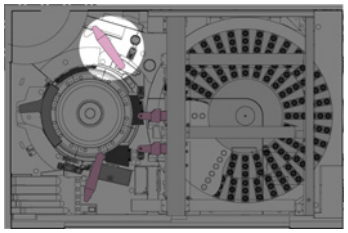
A Rack sampling position
B Sampling area
C Reaction disk area
D ISE area
E Reagent cassette loading port
F Reagent pipetters (pipetting area)
G Reagent area

Figure A-29 Areas of the **c** 501 module

The **c** 501 module can be subdivided into the following areas:

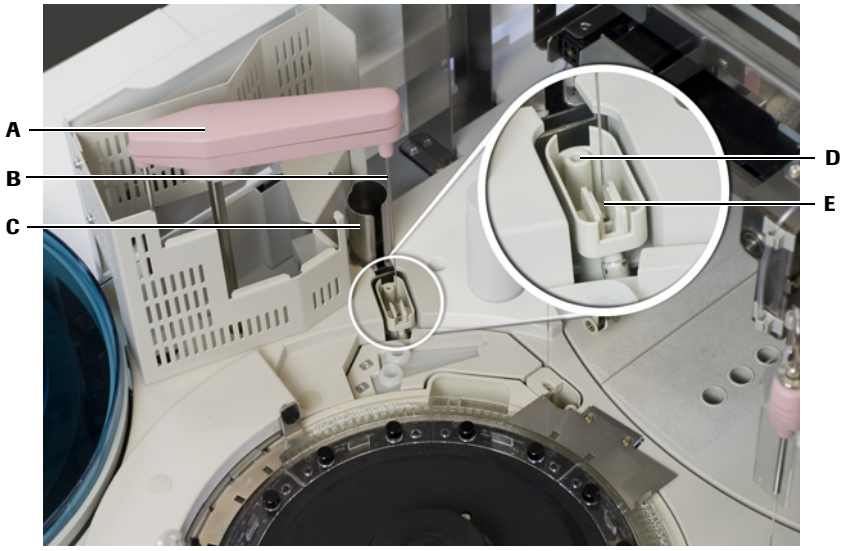
- Sampling area
 See *Sampling area components* on page A-70.
- Reagent area
 See *Reagent area components* on page A-72.
- Reaction disk area
 See *Reaction disk area components* on page A-77.
- Behind the front doors
 See *Behind the front doors* on page A-86.
- Rear side
 See *Rear view* on page A-88.
- ISE area
 See *ISE area components* on page A-89.

Sampling area components



The sampling area of the **c** 501 module consists of the following components:

- A rack sampling position.
- A sample pipetter (consisting of pipetter arm and probe) for pipetting samples from the sample tubes to the reaction cells on the reaction disk.
- A rinse station for internal and external rinsing of the sample probe.



A Pipetter arm
B Sample probe
C Shield pipe (against electrostatic noise)
D Drying cylinder (whole blood applications)
E Sample probe rinse station

Figure A-30 Sample pipetting system

Sample pipetter

The sample pipetter consists of the pipetter arm and the sample probe. When a rack is in the sampling position, the pipetter transports sample liquid from the sample tube to a reaction cell. When aspirating, liquid level detection is accomplished by a highly sensitive capacitance measurement, as well as clot detection by means of pressure measurements.

To protect the probe against electrostatic noise, which would interfere with the capacitance measurement, a metal shield pipe is mounted over the sampling position.

The sample probe is equipped with an extra sensitive level detection and clot detection. That is, it is not identical in construction and therefore not exchangeable with the ISE pipetter probe.

After sample has been aspirated, the probe is raised from the sample and is moved to the reaction disk. The sample probe arm lowers the probe into the reaction cell at the sample dispense position. Sample is dispensed while the beveled sample probe tip is in contact with the bottom of the reaction cell. This ensures that a precise volume of sample is deposited into the bottom of the cell even when using a low dispense volume. The sample probe is spring-mounted on the arm to avoid damage to the probe or reaction cell.

Sample probe rinse station

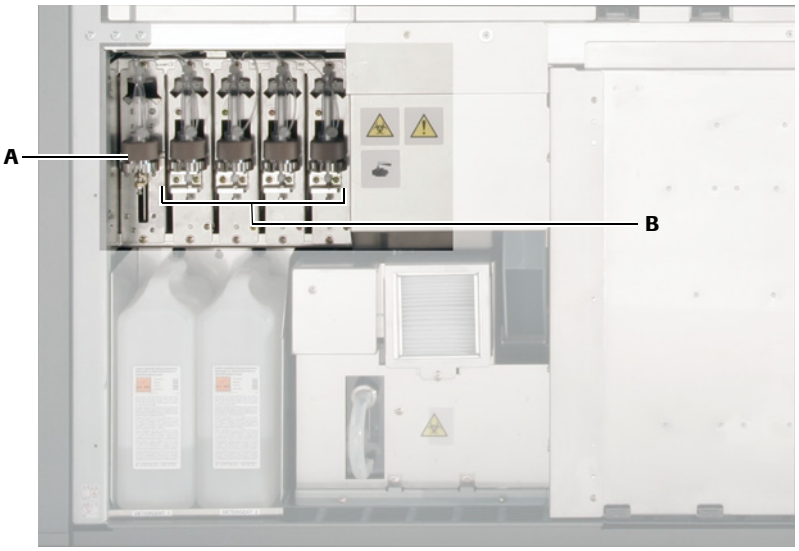
The sample probe rinse station is located between the sample aspiration position at the sample tubes in the sample racks and the sample dispense position at the reaction disk. To prevent carryover, the sample probe is rinsed here with deionized water both externally and internally before aspirating from a new sample.

The sample probe stops at the drying cylinder only when whole blood is pipetted for HbA1c tests.

The rinse station is the home position for the sample probe when the pipetter is in standby.

Sample syringe

The sample pipetter is connected by tubing to the sample syringe, which controls the pipetting action.



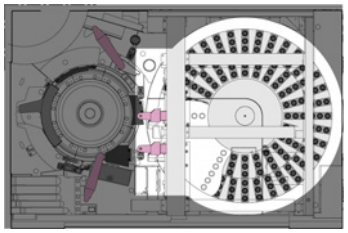
A Sample syringe **B** Reagent syringes

Figure A-31 Sample syringe

The sampling syringe, which is located behind the left front door of the module, is filled with degassed and deionized water. The syringe uses positive displacement to aspirate and dispense samples via the sample probes.

The syringe motor retracts the plunger within the chamber of the syringe, and sample is aspirated into the tip of the sample probe. The pipetter arm moves the sample probe to the reaction disk. The sample probe lowers into the reaction cell and the syringe motor reverses to dispense the sample. The pipetter arm lifts the sample probe from the reaction cell and moves it to the sample probe rinse station.

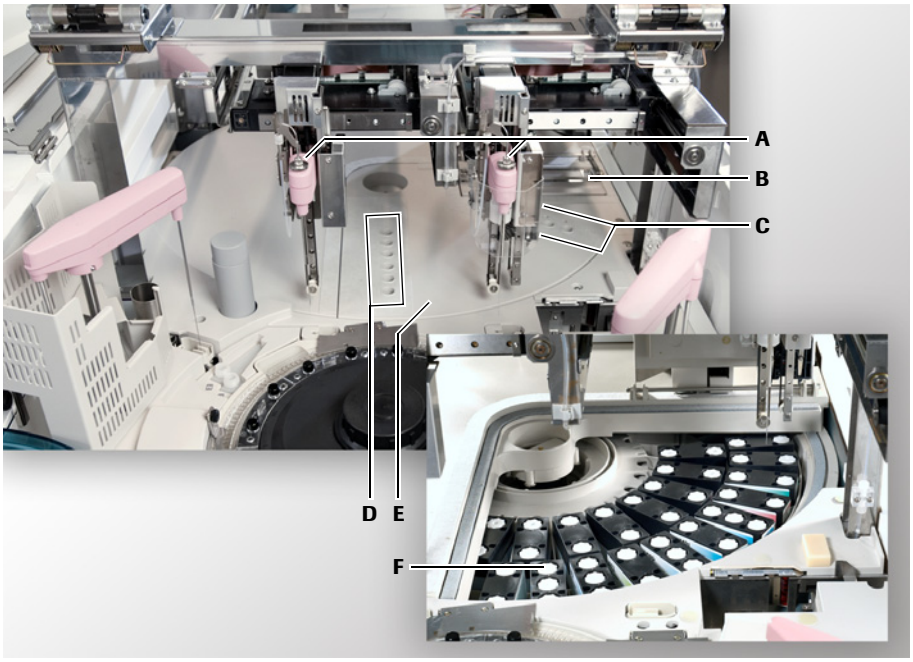
Reagent area components



The reagent area of the **c** 501 module consists of the following components:

- A refrigerated reagent compartment for storing up to 60 reagent cassettes.
- Two reagent pipetters for aspirating and dispensing reagents from the reagent compartment to the reaction cells on the reaction disk.
- Two rinse stations for internal and external rinsing of the reagent probes.
- A fully automated cassette management system

Reagent storage compartment



A Reagent pipetters
B Shutter
C Cutouts for R1 reagent pipetter probe
D Cutouts for R2 reagent pipetter probe
E Reagent compartment (cover closed)
F Reagent compartment (cover opened)

Figure A-32 Reagent storage compartment

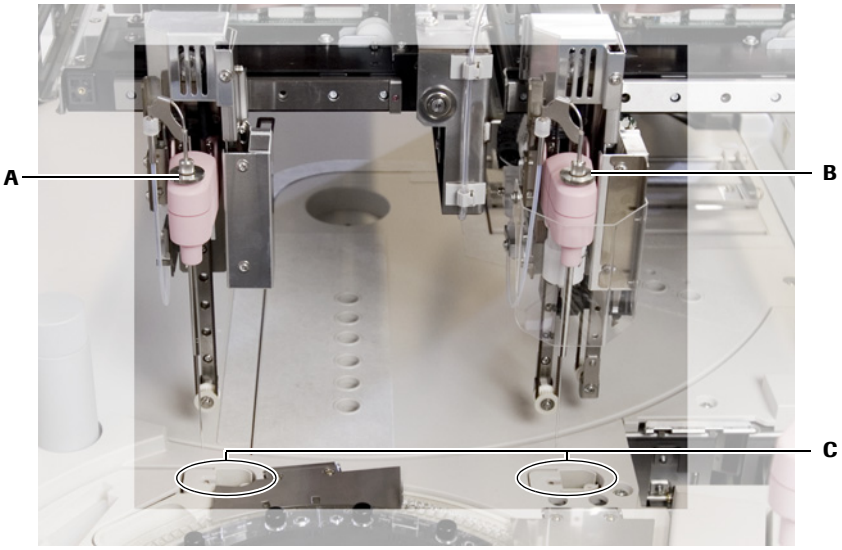
Reagent cassettes are stored in a closed, temperature-controlled (5-12°C) compartment containing two concentric rings with a total of 60 positions for reagent cassettes. There are 24 positions on the inner and 36 positions on the outer ring.

To prevent reagents from evaporating, the reagent compartment is equipped with a cover. By design, this cover is not meant to be opened or removed. Cassettes are placed into and removed from the compartment by way of the shutter and cutouts in the cover allow reagent probes to access the reagents.

Reagent pipetting system

The reagent pipetting system is composed of two reagent pipetters—R1 and R2—and two reagent syringes. The pipetters are mounted on two independent x-y-motion mechanisms.

Reagent pipetters



A R2 pipetter
B R1 pipetter
C Rinse stations

Figure A-33 Reagent pipetters

Two reagent pipetters, which are mounted above the reagent disk, transport the reagents from the reagent compartment to the reaction disk.

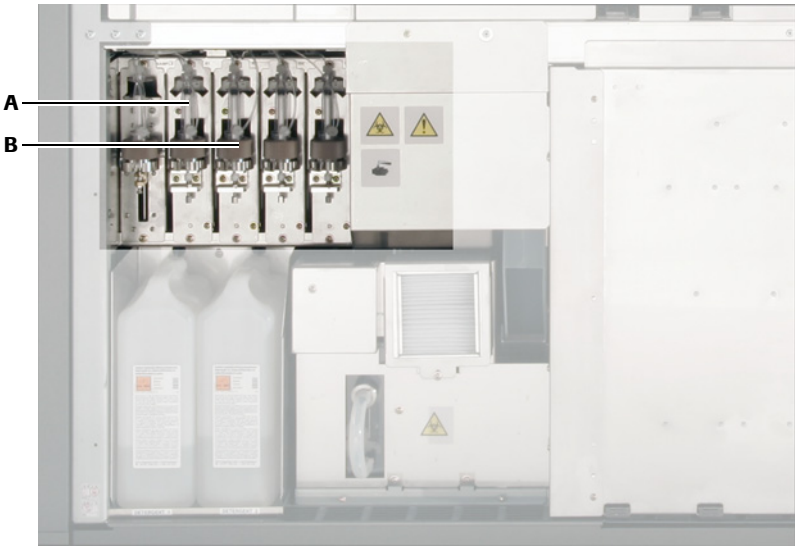
Before each pipetting, the reagent probes are externally and internally rinsed with deionized water and dried. After reagent has been aspirated, the probe moves from the reagent compartment to the reaction disk. There, the reagent volume is dispensed into a reaction cell containing the sample. Unlike the sample probe, the reagent probes are not lowered into the reaction cell. Reagent is dispensed from the top of the reaction cell.

The mechanical cycle of the **c** 501 module allows for three different reagent timings: R1, R2, and R3. The R1 pipetter pipettes reagents at R1 timing. The R2 pipetter pipettes reagents at R2 and R3 timing.

In contrast to R2, the R1 reagent probe is equipped with a pressure sensor to detect the reagent fill level of manually filled **cobas c** packs at the preparation station. Ready to use prefilled **cobas c** packs are not checked. The gripper and the piercer are mounted on the same x-y-motion mechanism as the R1 reagent probe.

See *Cassette preparation station* on page A-76.

Reagent syringes



A R1 syringe **B** R2 syringe

Figure A-34 Reagent syringes

The reagent syringes are located behind the left front door of the module. They are filled with degassed and deionized water, using positive displacement to aspirate and dispense reagents.

Reagent probe rinse stations

The reagent probe rinse stations are located between the reagent compartment and the reaction disk. After each reagent dispense, water is flushed through the probes and onto their outside surfaces. The probes are then dried at a drying cylinder.

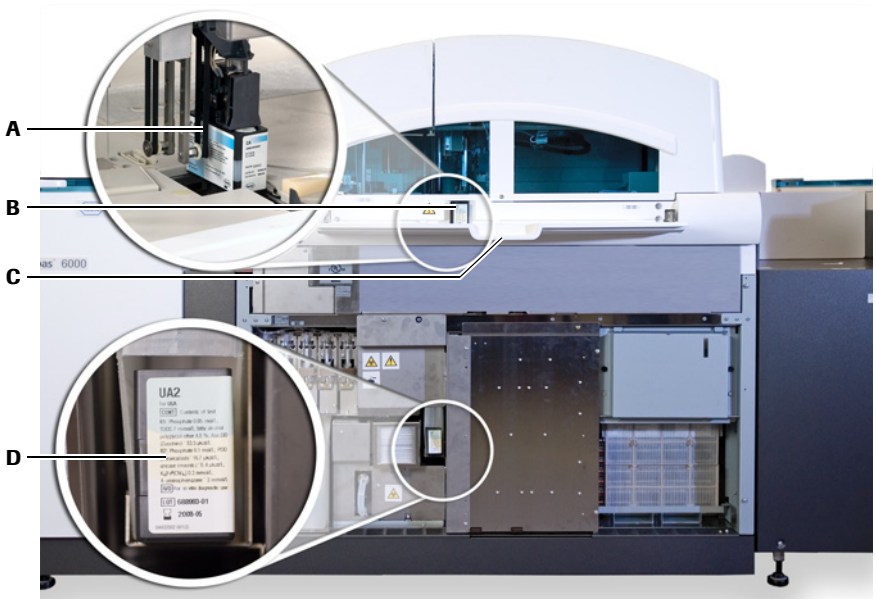
The rinse stations are the home position for the reagent probes when the module is in standby.

Cassette management system

Reagents for all Roche Diagnostics applications are provided in reagent cassettes. These cassettes contain one to three specially designed reagent bottles and carry barcode labels with detailed reagent and test related information.

From the time of check-in until an empty cassette is discharged the **c** 501 manages the registration, internal transportation, and placement fully automatically. This rules out any possibility of misplacement or usage of inappropriate reagents. The cassette management system consists of the following components:

- Cassette loading port
- Cassette preparation station
- Piercer and Gripper
- Cassette disposal



A Cassette preparation station
B Cassette loading port
C Cassette table
D Cassette disposal

Figure A-35 Components of the cassette management system

Cassette loading port

The cassette loading port is located behind the reagent cassette table at the front of the **c** 501 module. It is used for loading reagent cassettes onto the module.

When loading a reagent cassette, it is important that its **barcode label is facing to the right**.

After loading, the system handles the cassette without any further intervention of the operator: The cassette is pulled in to the preparation station where a barcode reader scans the cassette's barcode label and checks its integrity.

A cassette is rejected and not loaded but pushed out of the loading port again in the following cases:

- The cassette's barcode is unreadable
- The cassette has been on the analyzer before and it was previously dumped (discarded) by the system

Cassette preparation station

The cassette preparation station is located directly behind the cassette loading port. When a new cassette is pulled in to the preparation station, a barcode reader scans the following data from the cassette's barcode label:

- System-ID (for example, 07-3755-0)
- Lot number
- Production date
- Cassette number (serial number, for example, 01983)
- Expiration date
- Bottle configuration information

In case, the current cassette has been registered before, the shutter of the reagent compartment opens and the gripper loads the cassette.

If the current cassette is new, the system proceeds with the following actions while the cassette is at the preparation station:

- By reading the cassette barcode, the system checks the availability of the corresponding test application.
- The piercer pierces the reagent bottle caps.

 Now, the cassette is ready to be transported to the reagent compartment by the gripper.

Piercer and Gripper

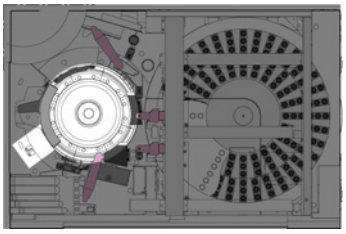
The piercer and gripper are mounted—together with the R1 pipetter—on an x-y-z motion mechanism. When a cassette is ready to be transported to the reagent compartment, the gripper lowers down on the cassette, grips it, lifts it, and moves it to the shutter. The shutter automatically opens and the cassette is placed in a registered position in the reagent compartment.

Cassette disposal

Empty reagent cassettes are automatically transported to the cassette disposal. With the aid of gravity, the cassettes drop down the cassette disposal shaft at the end of which they can be removed by the operator. The cassette disposal has a capacity of 10 cassettes.

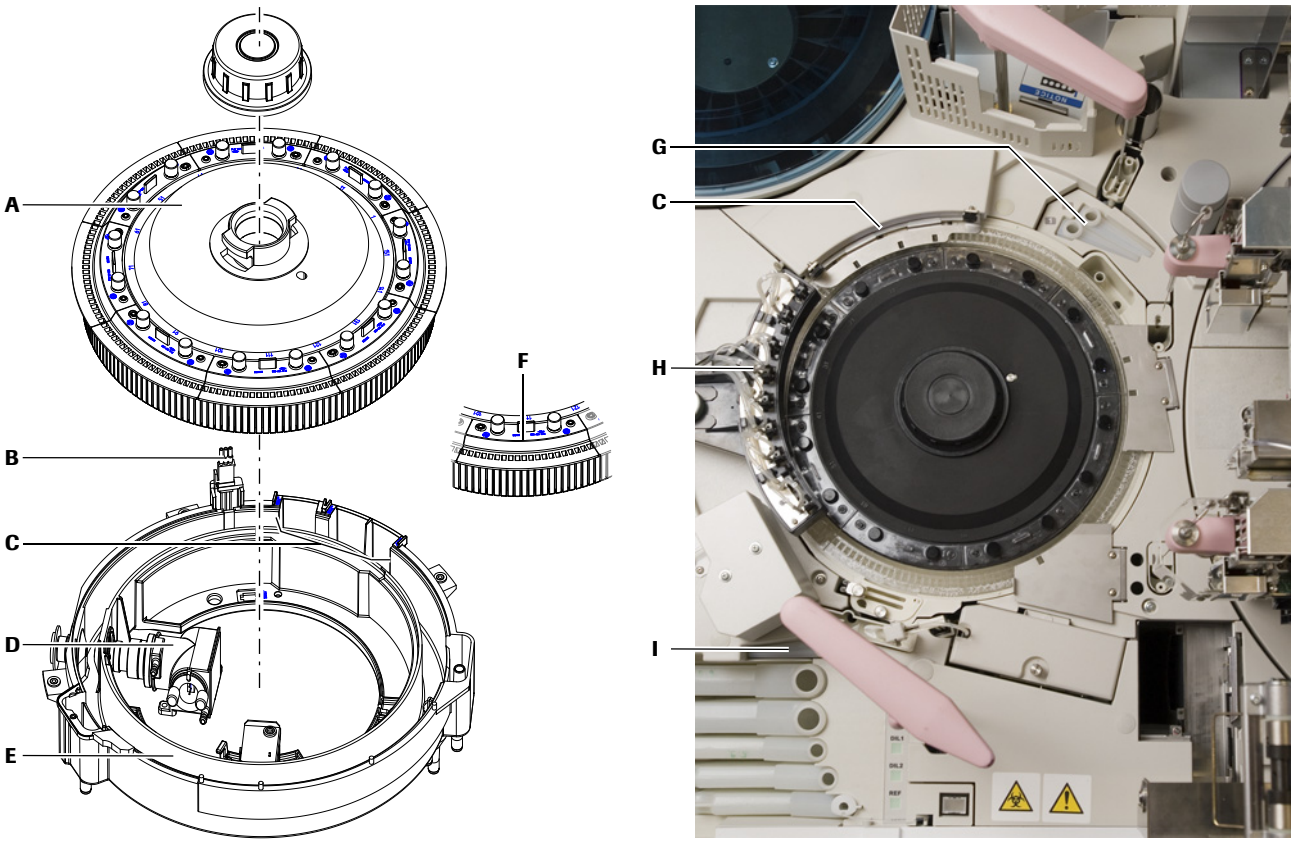
To locate the cassette disposal, see Figure A-35 on page A-75.

Reaction disk area components



The reaction disk area of the **c** 501 module consists of the following components:

- A reaction disk with the reaction cells, which are immersed in the incubator bath.
- Three ultrasonic mixing units for non-contact mixing of reaction mixtures (15 levels).
- A photometric measuring system which continually measures the absorbance of the reaction mixture in each of the reaction cells.
- A cell rinse unit for cleaning the reaction cells once test measurement is complete.
- The auxiliary reagents Sample Cleaner 2 (acid wash), Sample Cleaner 1 (basic wash), and EcoTergent.



A Reaction disk
B Water level sensor
C Ultrasonic mixing units
D Photometric unit
E Incubator bath
F Reaction cell segment
G (1) Sample Cleaner 1 (basic wash)
(2) Sample Cleaner 2 (acid wash)
H Reaction cell rinse unit
I EcoTergent

Figure A-36 Reaction disk area

Reaction disk

The reaction disk of the **c** 501 module carries 160 reusable plastic reaction cells (cuvettes). These reaction cells are grouped together in eight segments with 20 cells each. All reaction cells are placed in a temperature-controlled bath. This incubator bath maintains the cells at the required temperature of 37°C.

The reaction cells should be replaced once a month since they gradually deteriorate over time. Carry out cell blank measurement once a week after rinsing the reaction system to check the integrity of all cells.

For more information, see:
To perform a cell blank measurement on page C-78
Replacing reaction cells on page C-86

Ultrasonic mixers

The ultrasonic mixing units mix the reagents within each of the reaction cells to ensure a homogeneous distribution of reactants. Corresponding to the three reagent timings R1, R2, and R3, there are three independent mixing units.

To avoid spillage, the water level of the incubator bath is checked before mixing by calculating the volume. If the liquid level is too low or too high, an alarm (Mix.E) is issued and mixing is not performed.

Contamination on the surface of the ultrasonic mixing units causes inadequate mixing. It should be cleaned at least once every three months. The ultrasonic output intensity is continually monitored. If the intensity falls below a certain limit, an alarm (<Mix) is issued, and replacement of the ultrasonic mixing unit is required. Contact your Roche service representative for the replacement.

See *Cleaning the ultrasonic mixers* on page C-98.

Incubator bath

The circular incubator bath, positioned beneath the reaction disk, maintains the reaction mixtures in the reaction cells at a temperature of 37°C. Water in the incubator bath is circulated by a pump through a refrigeration unit where it is cooled and then onto the heater where it is heated, as necessary, to maintain the temperature (±0.1 °C).

Two glass windows (inner and outer) are positioned in opposite walls of the incubator bath. These windows permit light from the photometer lamp to pass through the incubator bath water and through the reaction cells in the bath. The light beam emerges from the outer window of the incubator bath and enters the instrument photometer.

A liquid level sensor detects the water level of the bath. Deionized water is automatically added to the incubator bath, as determined by the liquid level sensor, to compensate for evaporation. This occurs even in standby.

Bath detergent

EcoTergent is a non-ionic, bacteriostatic detergent automatically added to the incubator bath by the ISE pipetter whenever the water is exchanged. It acts as a surfactant to minimize the formation of bubbles that could potentially interfere with the photometer readings. EcoTergent is located between the ISE reagent compartment and the reaction disk. EcoTergent is the substitute product to the previously used Hitergent.

To locate the reagent bottle for EcoTergent, see Figure A-36 on page A-77.

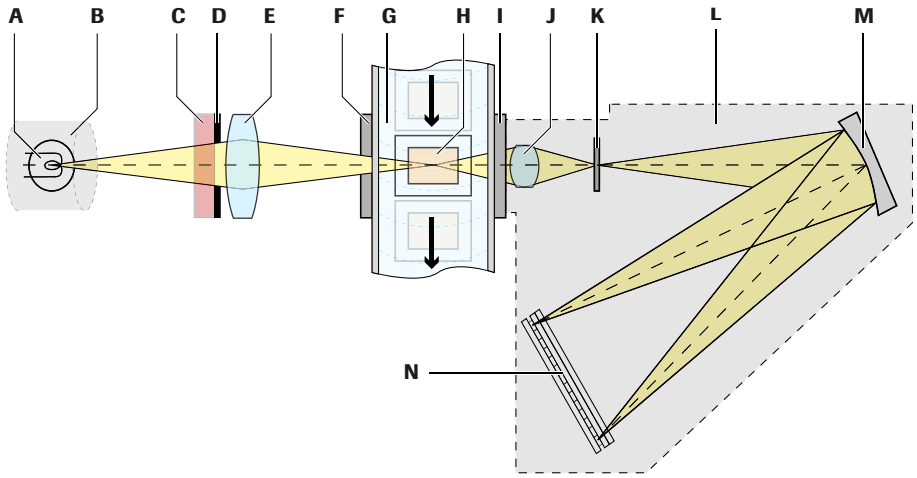
Photometer

The **c** 501 module is equipped with a photometer to measure the absorbencies of the reaction mixtures in the reaction cells.

The photometer lamp is located against the inner ring of the incubator bath beneath the reaction disk. The detector is outside the incubator bath ring, behind the ISE reagent compartment.

To locate the photometer unit, see Figure A-36 on page A-77.

Measurements are taken of all the 160 reaction cells, as the reaction disk is turning.



A	Photometer lamp	**F**	Slit (in)	**K**	Slit
B	Water jacket	**G**	Incubator bath	**L**	Photometer
C	Infrared cut filter	**H**	Reaction cell and contents	**M**	Grating
D	Mask	**I**	Slit (out)	**N**	Detector
E	Condenser lens	**J**	Imaging lens		

Figure A-37 Illustration of light path through photometer components

Photometer lamp

The photometer lamp beneath the reaction disk, is encased in a constant-temperature water jacket, which helps to maintain a constant energy output from the lamp, and also extends the lamp life.

For more information about replacing the photometer lamp, see *Replacing the photometer lamp* on page C-108.

Light path

The light from the photometer lamp passes through the following main components:

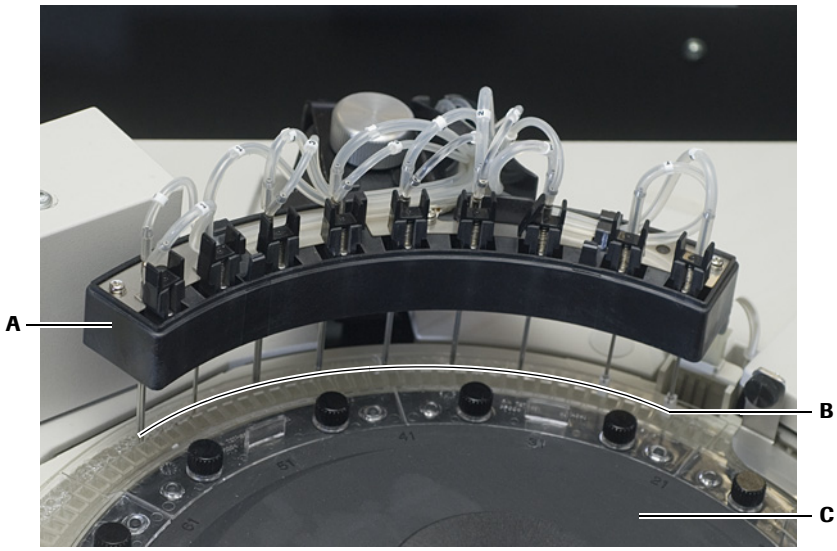
- Inner incubator bath window
- Incubator bath water
- Reaction cell and its contents
- Incubator bath water
- Outer incubator bath window
- ...and into the photometer

When the light beam enters the photometer, it strikes a diffraction grating. This separates the light into its constituent wavelengths and reflects them onto a fixed array of 12 photodiodes. Each photodiode is permanently positioned to detect light at a different wavelength.

The instrument computer uses the available assay parameter information to select the wavelengths and the times at which a reaction mixture's absorbance is read and results are calculated.

The instrument computer keeps tracks of which test is being performed in each reaction cell. The instrument computer also knows when each reaction cell passes through the photometer light path. The instrument computer uses this tracking ability and the programmed read instructions to obtain test results.

Cell rinse unit



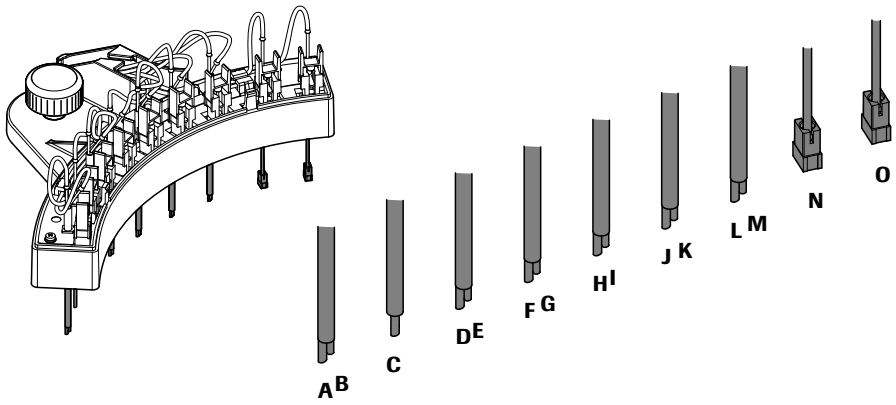
A Cell rinse unit
B Cell rinse nozzles
C Reaction disk

Figure A-38 Reaction cell rinsing system

The cell rinse unit is located to the left of the reaction disk. It cleans, rinses, and dries the reaction cells once the chemical reaction of the reaction measurement is completed. To ensure cell integrity (optical characteristics), a photometric reading of the cell containing water is performed during the cleaning process (cell blank) and compared with the stored value from the weekly cell blank measurement.

Cell rinse sequence

The following sequence reflects the order in which cleaning, rinsing, and cell blanking of the reaction cells takes place.



1. L: Liquid aspiration at end of reaction
 M: Rinse water discharge
2. J: Rinse water aspiration
 K: CellCln 1 discharge
3. H: CellCln 1 aspiration
 I: CellCln 2 discharge
4. F: CellCln 2 aspiration
 G: Rinse water discharge
5. D: Rinse water aspiration
 E: Rinse water discharge
6. C: Rinse water aspiration
7. A: Water blank discharge
 B: Water blank overflow aspiration
8. N: Water blank aspiration (nozzle tip)
 O: Water blank aspiration (nozzle tip)

Figure A-39 Flow of the cell rinse mechanism

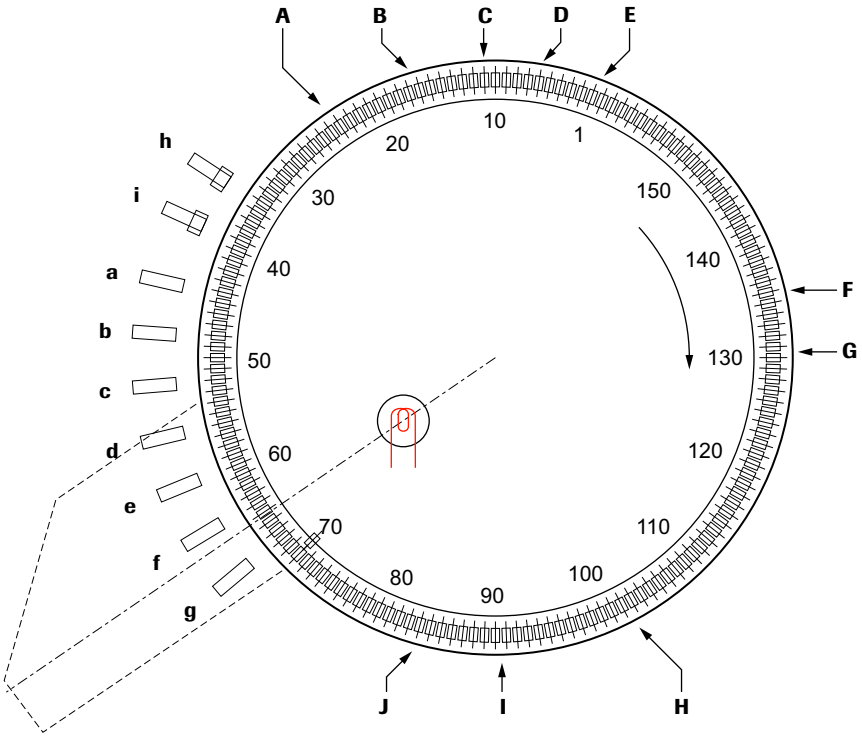
Flow of photometric analysis

The following sections help to understand the flow of photometric analysis:

- *Main functions on the reaction disk area.*
- *Main steps of photometric analysis*

Main functions on the reaction disk area

The main function and their positions on the reaction disk area are shown below.



a–i Cell rinsing nozzles
A Reagent 1 mixing
B Reagent 2 mixing
C Reagent 3 mixing
D Sampling (diluted sample)
E Sampling
F Reagent 2 adding
G Reagent 3 adding
H Reagent 1 adding
I Sampling diluted sample for ISE
J Diluting sample for ISE

Figure A-40 Main functions and their positions on the reaction disk area

Main steps of photometric analysis

The main steps of photometric analysis flow are shown below.

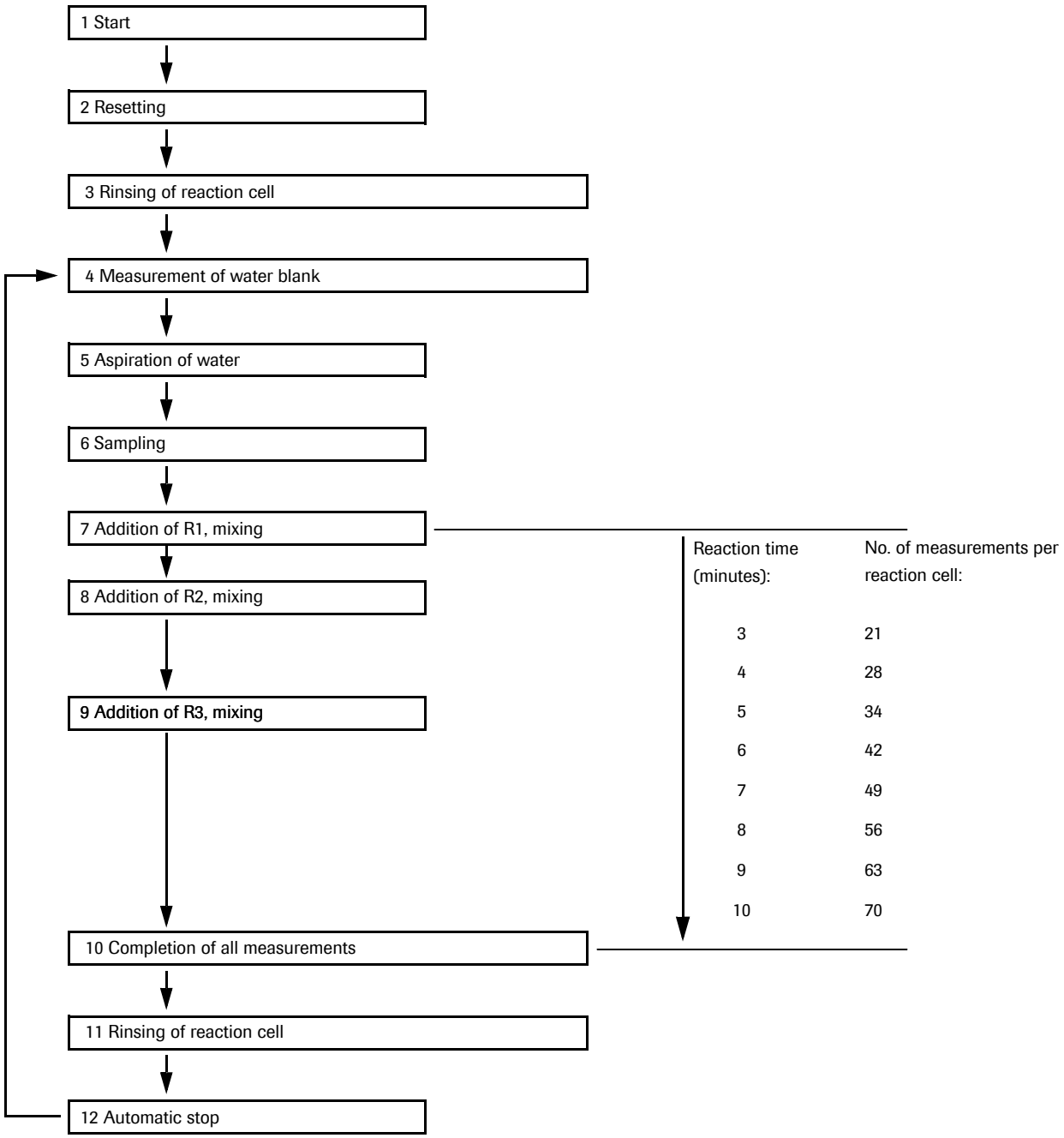


Figure A-41 Flow chart of the photometric analysis

Step	Action
1–2	Upon start, the instrument resets the mechanisms, and then starts rinsing the reaction cell.
	In a single cycle (6.0 s), the reaction disk rotates by 60 reaction cells, stops temporarily, and rotates by a distance of 59 reaction cells. Therefore, the reaction disk rotates 3 turns minus 4 reaction cells in 4 cycles (24.0 s)
3	• Using the rinsing nozzle **a** in the rinsing mechanism, reaction solution is aspirated and the reaction cell is rinsed with deionized water. • Then, after 4 cycles, the reaction cell is washed with rinsing nozzle **b** in the rinsing mechanism using Cell Wash Solution I / NaOH-D. • Then, after 4 cycles, the reaction cell is washed with rinsing nozzle **c** in the rinsing mechanism using Cell wash Solution II / Acid Wash. • Using the rinsing nozzle **d** and the rinsing nozzle **e**, the reaction cell is rinsed again with deionized water. • After deionized water is aspirated with nozzle **f**, rinse water is discharged with nozzle **g**.
4	Then water blank is measured 3 times. If the water blank value differs by 0.1 or more from the cell blank value, that cell is not used for analysis.
5–6	After the water blank measurement, the water is aspirated (using rinsing nozzles **h** and **i**) and the cells are dried and ready for measurement. Sampling is carried out in the order starting from the sample with the test that takes the longest reaction time in order to shorten the time needed for completion of data output.
7–9	Reagents R1, R2, and R3 are usable, and added at the determined positions and time points (0, 1.5 and 5 minutes), respectively. After one of the reagents R1, R2, and R3 has been added, the liquid in the cuvette is mixed at the corresponding mixing position by means of the ultrasonic mixer.
10	Sampling is carried out every 6 s (1 cycle), and measurement is performed once in every full turn, that is 70 times in 10 minutes. On completion of measurement, the concentration is calculated by using the absorbance at the specified measuring point.
11	The instrument discharges the reaction solution with the rinsing mechanism and conducts washing with detergent and rinsing with water.
12	Then the instrument goes into standby.

Table A-5 Flow of photometric analysis

Reaction monitoring

The **c** 501module adopts the entire reaction monitoring system, which measures the absorbance of reaction solution intermittently during reaction time. The reaction disk rotates 3 turns in 24 seconds. During this time, the absorbance is measured and stored for all of reaction cuvettes that go across the optical path of the photometer. For each reaction cuvette, water blank (absorbance 0) is measured, and then photometry is performed about every 8 seconds, or 70 times in 10 minutes. Analysis method can be set flexibly by using arbitrary measuring points for concentration calculation.

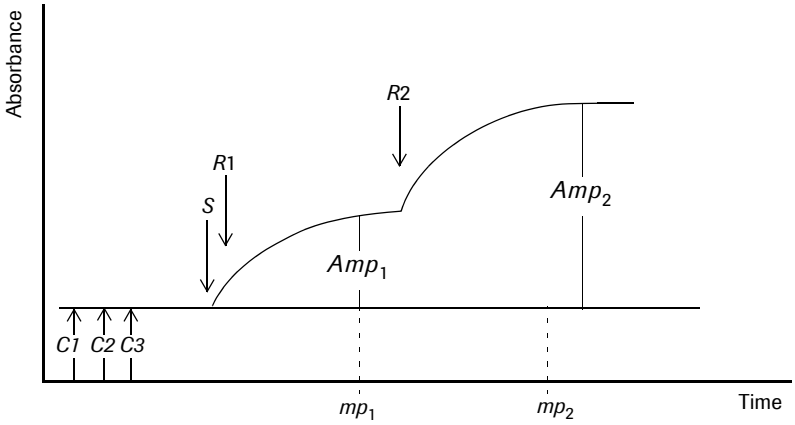
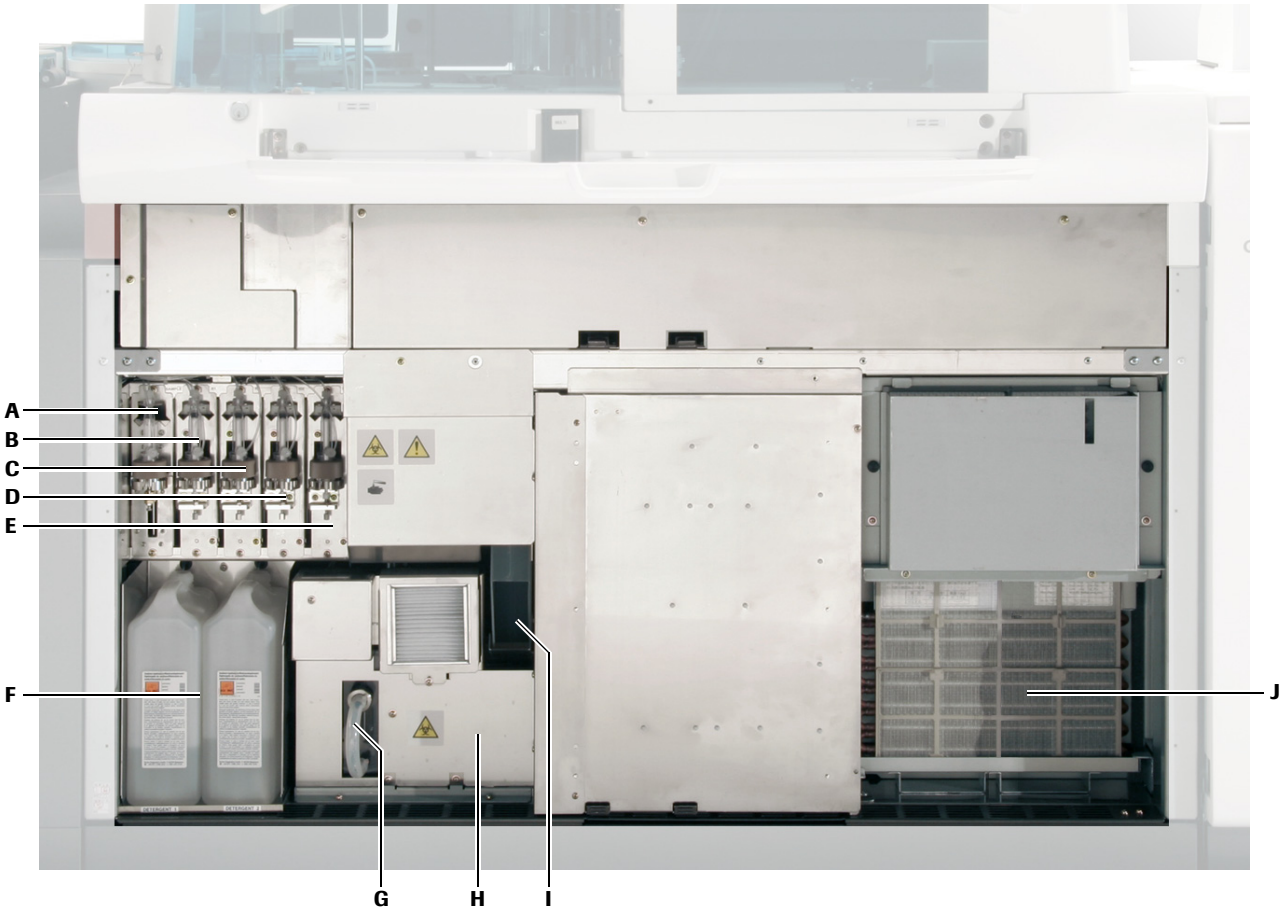


Figure A-42 Reaction course

Behind the front doors

Figure A-43 provides a front view of the **c** 501 module and lists the main components behind the front doors of the module.



A	Sample syringe	**E**	ISE sipper syringe	**G**	Vacuum tank
B	Reagent 1 syringe	**F**	Cell detergents:	**H**	Vacuum pump
C	Reagent 2 syringe		Cell Wash Solution I / NaOH-D and	**I**	Reagent cassette disposal
D	ISE probe syringe		Cell Wash Solution II / Acid Wash	**J**	Cooling unit with radiator filter

Figure A-43 **c** 501 module with open front doors

Auxiliary reagents and cleaning solutions

Auxiliary reagents of the **c** 501 module are located both behind the front door and in the reaction disk area:

- Two large bottles with detergents for the cell rinse process are located behind the left front door of the **c** 501. They contain Cell Wash Solution I / NaOH-D (Cell Wash Solution I / NaOH-D) and Cell Wash Solution II / Acid Wash (Cell wash Solution II / Acid Wash).
- Two small bottles (70 mL) containing Sample Cleaner 1 and Sample Cleaner 2 are located close to the sample pipetter, and one bottle of EcoTergent is located close to the ISE pipetter.
 - Sample Cleaner 1 and Sample Cleaner 2 are used for cleaning the sample probe.
 See Figure A-36 on page A-77 (**G**).
 - EcoTergent is an additive to the incubator bath to reduce surface tension and microbial proliferation.
 See Figure A-36 on page A-77 (**I**).

For more information about auxiliary reagents, see *Auxiliary reagents* on page B-111.

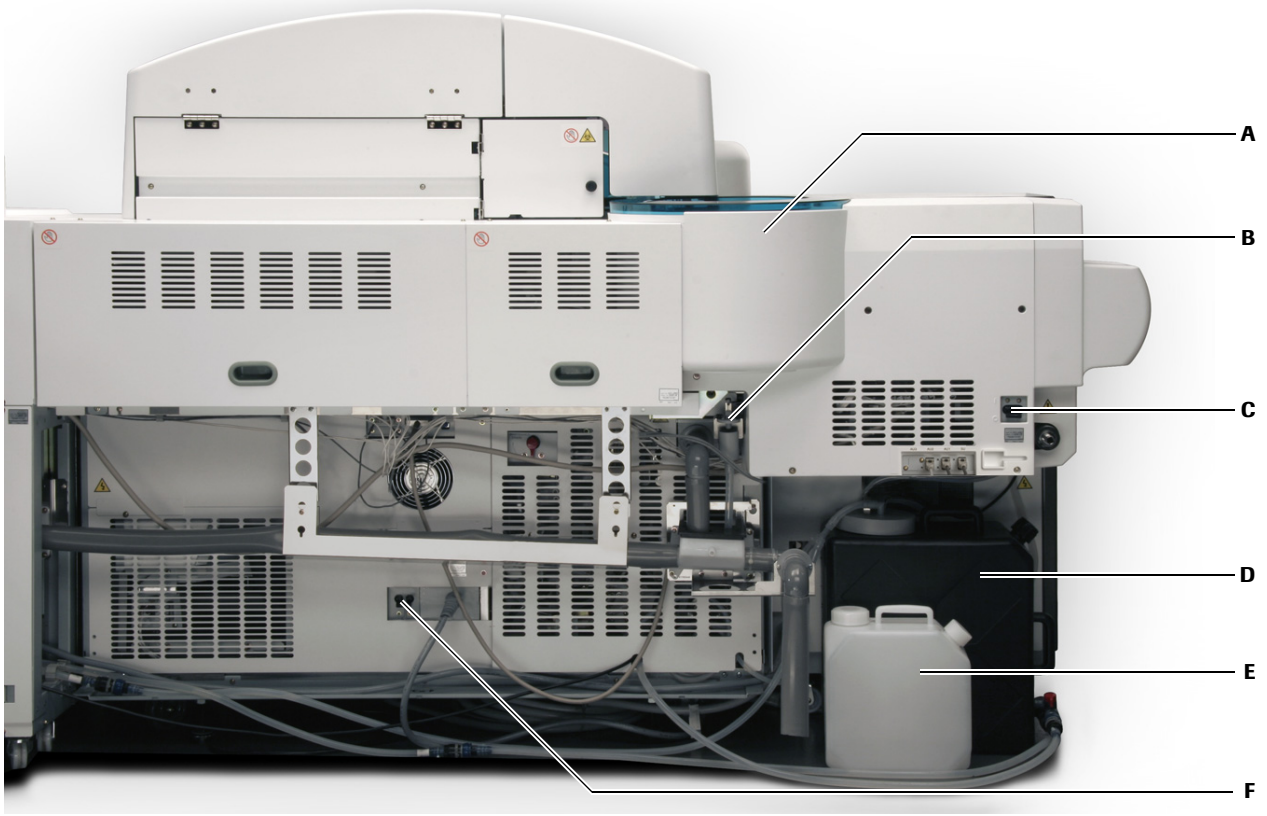
Vacuum system

The vacuum system is located at the front of the module. It consists of vacuum pump, vacuum tank, vacuum sensors, and connecting tubing. The vacuum system aspirates reaction mixture waste from the reaction cells to the reaction waste container and removes reaction cell rinse water from the module through the main drain line.

To locate the vacuum system, see Figure A-43 on page A-86.

Rear view

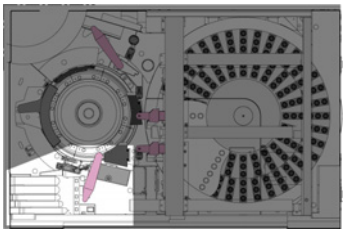
Figure A-44 provides a rear view of the **c** 501 module assembled with a **cu** 150 core unit. The legend lists the main components on the back of the analyzer.



A Rack rotor
B Drain port (connected to the drain pipe)
C Core unit module switch
D Water tank
E High concentrated waste
F **c** 501 module switch

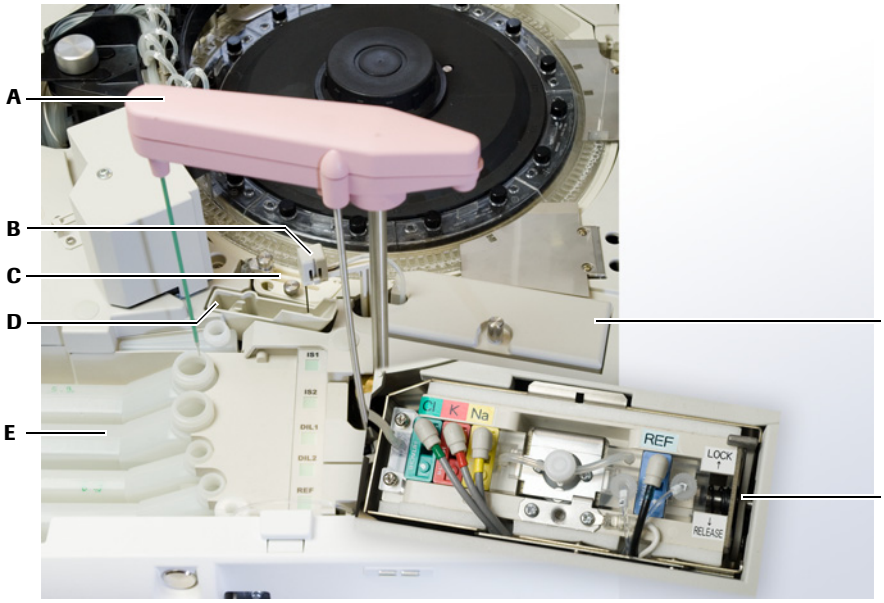
Figure A-44 **c** 501 rear view

ISE area components



The ISE unit provides an electronic method for measuring sodium, potassium, and chloride ion activities in samples. It is designed to process up to 600 tests or 200 samples per hour. The ISE unit of the **c** 501 module consists of the following components:

- ISE pipetting system
- Internal standard bath (IS bath)
- ISE sipper mechanism
- ISE measuring system
- ISE rinse station
- ISE reagent compartment



A ISE pipetter
B ISE sipper
C IS baths
D ISE rinse station
E ISE reagent compartment
F Cover of the ISE measuring system
G ISE measuring system

Figure A-45 **c** 501 ISE unit

The ISE area of the **c** 501 module comprises the following components:

- One internal standard bath with two chambers (IS bath)—for heating internal standard (ISE IS) to measuring temperature (37°C)
- ISE pipetting system
- ISE sipper mechanism—for aspirating ISE IS and sample solution into the measuring system
- ISE reagent compartment—containing bottles for ISE IS, ISE Dil., and ISE Ref. (KCL)
- ISE measuring system

ISE pipetting system

The ISE pipetting system is composed of a pipetter (consisting of pipetter arm and probe), a syringe, and the ISE rinse station. The pipetter is connected by tubing to the syringe, which controls the pipetting action.

ISE pipetter probe The ISE pipetter probe is equipped with a level detector (capacitance method). These features are similar to the sample probe, however, ISE and sample probes are not equal in construction and cannot be exchanged.

ISE syringe The ISE syringe is located behind the left front door of the **c** 501 module. It is the fourth syringe (from left to right), between the R2 and the sipper syringe.

ISE rinse station The ISE rinse station is located between the IS bath and the reagent compartment. This rinse station is used for both ISE pipetter probe and sipper probe.

Internal standard bath

Internal standard bath (IS bath) has two chambers for heating internal standard (ISE IS) to measuring temperature (37°C). The use of two chambers allows an optimized flow of the analysis: While the content of one chamber is ready for use, fresh ISE IS is pipetted into the other chamber where it is given time to heat up for the next measurement.

ISE sipper mechanism

The ISE sipper mechanism consists of a sipper nozzle and a sipper syringe.

Sipper nozzle The sipper nozzle lowers either into ISE IS solution in the IS bath or into sample solution in a reaction cell to aspirate the respective solution into the measuring flow path.

Sipper syringe The sipper syringe is positioned behind the left front door of the **c** 501 module. It is the rightmost syringe (to the right of the ISE reagent syringe). The syringe not only provides the negative pressure for the sipper but also aspirates ISE Ref. from its container and into the reference cartridge flow path.

ISE measuring system

The ISE measuring system is—together with the IS bath—contained in a temperature-controlled compartment. It is composed of three channeled sample/ISE IS measurement cartridges and one reference cartridge.

Measurement cartridges

Three cartridges, each containing an ion-selective electrode, are directly connected to form a flow path for the diluted sample and the ISE IS solutions. The electrode potentials are measured in the color-coded cartridges as follows:

Red	Potassium	K^+
Yellow	Sodium	Na^+
Green	Chloride	Cl^-

Reference cartridge

The reference cartridge contains the reference electrode. ISE Ref. is aspirated through the cartridge and a reference electrode potential is registered.

The difference between the potentials at the reference electrode and the ion-selective electrode equals the electromotive force (EMF). For every test, the EMF of both ISE IS and diluted sample solution are measured for each sort of ions (Cl^-, K^+, and Na^+). From these EMF values the results are calculated.

ISE rinse station

At the ISE rinse station both ISE pipetter probe and sipper probe are rinsed with deionized water. To avoid contamination, clean the rinse station at least once a week.

See *Cleaning the rinse stations* on page C-81.

ISE reagent compartment

The ISE reagent compartment provides five positions for reagent bottles: Two positions for ISE IS, two for ISE Dil., and one for ISE Ref. bottle.

The reagent compartment is equipped with position sensors for each reagent bottle (reflection type).

A green indicator lamp (next to the reagent position) lights up if no reagent bottle is present or if the liquid level falls below the limit where the bottle needs to be replaced. In this case the ISE probe pipettes from the second bottle of the reagent (changeover reagent). If the second bottle of ISE IS is used as changeover reagent, a changeover calibration is automatically recommended by the system.

For more information on level detection and ISE reagent registration, see:
ISE pipetting system on page A-90
Reagents for ISE applications on page B-105

Flow of an ISE analysis

At the beginning of an electrolyte analysis, the sample pipetter pipettes a sample into a reaction cell. Then, into this cell, ISE Dil. is pipetted by the ISE pipetter and mixing is carried out with the ultrasonic mixing unit. Next, the ISE pipetter dispenses ISE IS solution into the IS bath where it is heated to 37°C.

After heating, the ISE IS solution is aspirated into the measuring flow path to perform an ISE IS measurement (single-point calibration). The residual ISE IS solution is aspirated through the vacuum nozzle to empty the IS bath. Then, the sipper aspirates diluted sample from the reaction cell and the sample measurement is performed.

For every ISE measurement, the analyzer measures three electromotive force values (EMF); for chloride, potassium, and sodium, where EMF denotes the difference in potential between the respective ion-selective electrode and reference electrode.

Finally, the results are calculated from the electromotive forces of ISE IS and diluted sample. The ISE system is now ready for the next analysis. If there are no more samples to be analyzed, the ISE unit performs a final ISE IS measurement and stops. Table A-6 summarizes the flow of an ISE analysis:

Step	Time	Actor	Action
		Preparation of measurement	
1	0.0 s	Sample pipetter	Pipettes sample (9.7 µl) to cell
2	12.0 s	ISE pipetter	Aspirates (348 µl) and dispenses ISE Dil. (291 µl) to cell
3	15.0 s	Ultrasonic mixing unit	Mixes sample and ISE Dil.
4		ISE pipetter	Aspirates (590 µl) and dispenses ISE IS (450 µl) to IS bath
5		IS bath	ISE IS heats to measuring temperature (37°C)
		Internal standard (ISE IS) measurement	
6	284.5 s	ISE Sipper	Aspirates ISE IS to Cl/K/Na electrodes (400 µl)
7		Sipper syringe via tubing	Aspirates ISE Ref. from the ISE Ref. bottle to reference electrode (65 µl)
8	292.0 s	Electrodes	Measure ISE IS
		Diluted sample measurement	
9	301.0 s	ISE Sipper	Aspirates sample to Cl/K/Na electrodes (250 µl)
10		Sipper syringe via tubing	Aspirates ISE Ref. from the ISE Ref. bottle to reference electrode (65 µl)
11	310.0 s	Electrodes	Measure sample
		Finalization of measurement	
12	315.0 s		Result calculation and output If there are more samples to be analyzed, go to step 1. If there are no more samples, repeat 6-8 and stop.

Table A-6 Flow of ISE analysis

e 601 module

This chapter provides a detailed description of the **e** 601 module, its components and technical specifications. In addition, an overview of the reagents used on the **e** 601 module is provided.

In this chapter *Chapter* 5

Overview A-95
System characteristics A-95
Components of the e 601 module A-96
Reagent area components A-97
Reaction area components A-99
Pre-wash area components A-101
Consumables area components A-103
Auxiliary reagents and cleaning solutions A-106

Overview

The **e** 601 module is a fully automated analyzer for immunoassay analysis. It is designed for both quantitative and qualitative in vitro determinations using a large variety of tests for analysis. Samples are transported to the **e** 601 module by the core unit of the **cobas** 6000 system.

The throughput of the **e** 601 module is up to 170 tests per hour.



Figure A-46 **e** 601 module

This chapter describes the **e** 601 module. The rack rotor and rack sampler unit belong to the core unit.

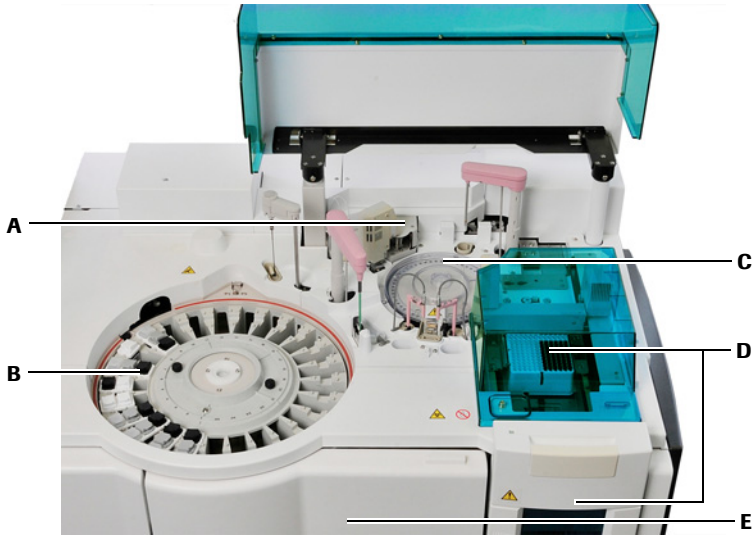
For a detailed description of the core unit, see Chapter 3 *Control unit, cobas link and core unit*.

System characteristics

- Heterogeneous immunoassays with ECL technology
- 2 ECL measuring cells
- 170 tests/hour throughput on one **e** 601 module
- Storage for 25 **cobas e** packs on one **e** 601 module
- Disposable tips for sample pipetting to prevent carryover
- Incubator disk with 54 incubator positions (37°C)
- Non-invasive vortex mixer
- Automated maintenance functions
- Automatic rerun capability
- Automatic calibration notification
- Automatic sample dilution capabilities

Components of the e 601 module

Figure A-47 shows the different areas of the **e** 601 module from a top-view perspective:



A Pre-wash area
B Reagent area
C Incubator
D Consumables area
E Auxiliary reagents area (behind the front doors)

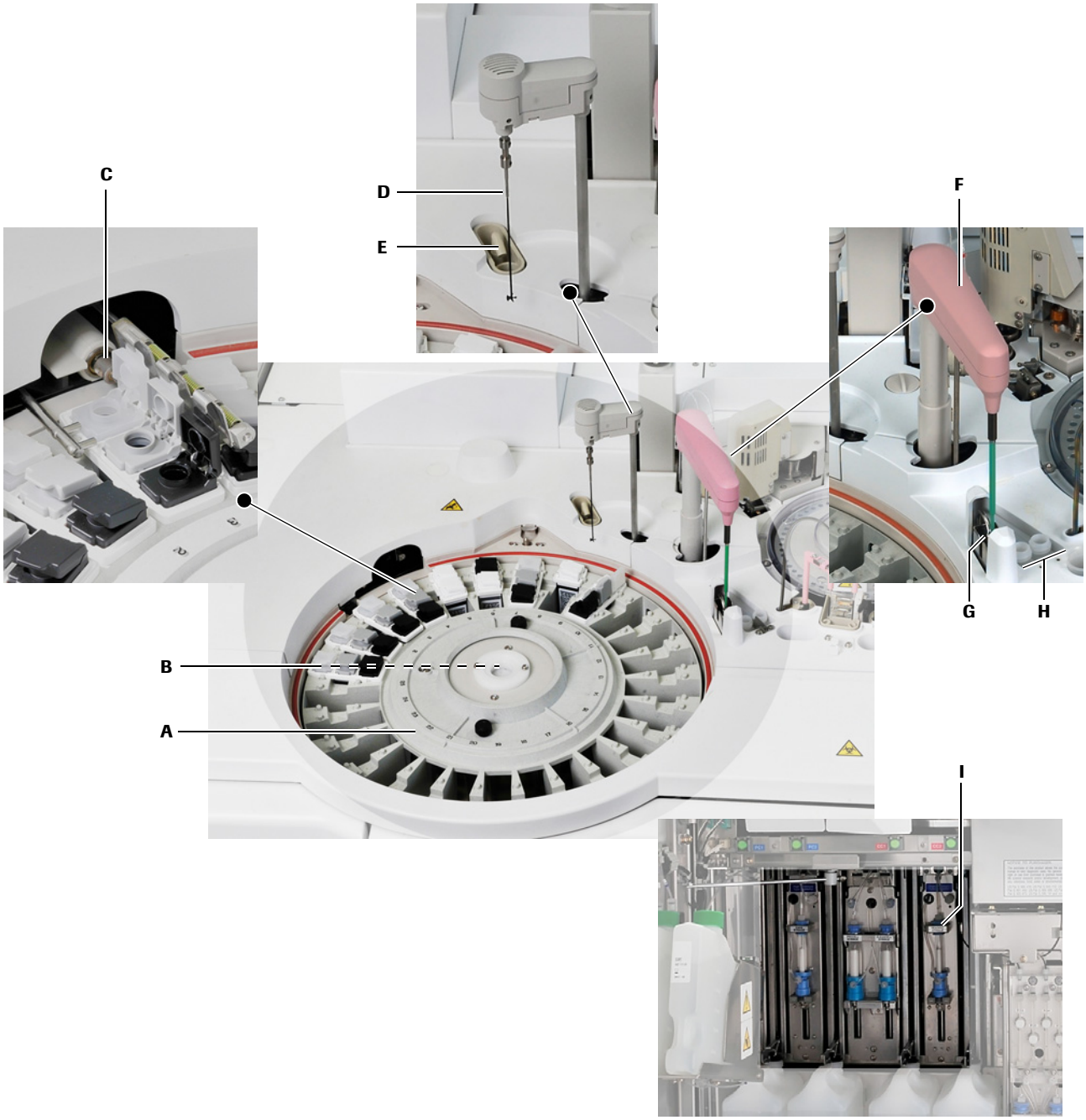
Figure A-47 **e** 601 module: top view

The **e** 601 module can be subdivided into the following areas

- Reagent area
 See *Reagent area components* on page A-97.
- Reaction area
 See *Reaction area components* on page A-99.
- Pre-wash area
 See *Pre-wash area components* on page A-101.
- Consumables area
 See *Consumables area components* on page A-103.
- Auxiliary reagents area (behind the front doors)
 See *Auxiliary reagents and cleaning solutions* on page A-106.

Reagent area components

The reagent area is on the left side of the analytical module and consists of the following components:



A Reagent disk
B Barcode reader
C Reagent Cap Open/Close mechanism
D Microbead mixer
E Microbead mixer rinse station
F Reagent probe
G Reagent probe rinse station
H ProbeWash station
I Reagent syringe

Figure A-48 Reagent area components

Reagent disk

The reagent disk is located on the left side of the analytical module and contains 25 positions for assay, diluent or pretreatment **cobas e** packs. The reagent disk is temperature controlled at 20 ±3 °C.

Diluent or pretreatment reagents can be placed in ANY position on the reagent disk. More than one **cobas e** pack can be loaded on the reagent disk for each test at any time.

Barcode reader

The barcode reader is located in the center of the reagent disk and reads the 2D matrix barcode on the **cobas e** packs.

Reagent Cap Open/Close mechanism

To prevent reagents from evaporating, and for ease of use, the reagent disk utilizes a reagent cap open/close mechanism during reagent pipetting. The mechanism is located on the back wall of the reagent disk compartment and emerges when **cobas e** packs need to be opened or closed. The system can be configured to open caps prior to pipetting or mixing the specific reagent (for example, M, R1 or R2) and close them again afterwards, or to leave the cap open during operation.

Soft-close position of caps

Before loading a reagent pack, open the caps manually and set them gently to the so called soft-close position: The caps are almost closed, but not tightly closed. This ensures the caps can be opened by the mechanism.

See *Caps of cobas e pack* on page B-116.

For information about cap opening and closing, see *Cap Open/Close Mode area* on page E-493.

Microbead mixer with rinse station

The microbead mixer, located beside the reagent disk, mixes the microbeads to ensure a homogeneous suspension before aspiration.

The microbead mixer rinse station rinses the microbead mixer with deionized water each time it has been used.

Reagent probe with rinse station

The reagent pipetter, located between reagent disk and incubator, aspirates reagent from the **cobas e** packs on the reagent disk and dispenses it into the AssayCups in the incubator. To prevent reagent carryover, the reagent probe is rinsed after each pipetting operation at the rinse station. The reagent probe also has liquid level sensing for accurate pipetting.

The reagent probe rinse station rinses the reagent probe externally and internally with deionized water between aspirations.

ProbeWash station

The ProbeWash station, located on the analytical module near the reagent probe, consists of two bottles of ProbeWash. ProbeWash is used to wash the inside of the reagent probe to prevent carryover.

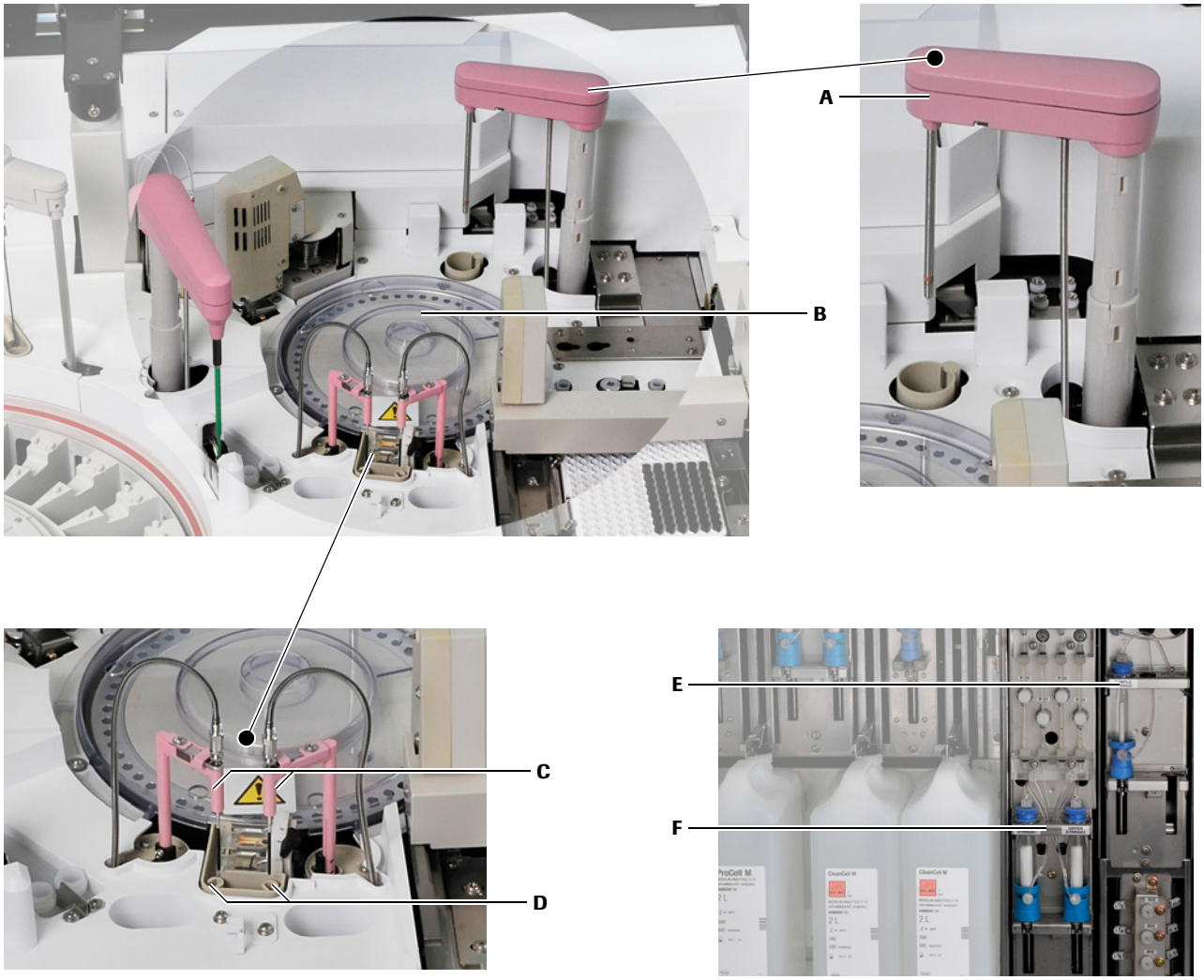
For information about special wash, see *Special Wash* on page B-297.

Reagent syringe

The reagent syringe is located on the right behind the front door of the analytical module. The syringe is filled with deionized water and uses positive displacement to aspirate and dispense from the reagent probe.

Reaction area components

The reaction area is in the middle of the analytical module and consists of the following components:



A Sample probe
B Incubator disk
C Sipper probes
D Sipper probe rinse stations
E Sample syringe
F Sipper syringes

Figure A-49 Reaction area components

Sample probe The sample probe is located at the back of the analytical module near the core unit. The sample probe transports the sample, calibrator or control fluids from the sample tubes in the racks at the sampling position into the AssayCups in the incubator. The probe uses a new disposable tip for every pipetting sequence to prevent carryover and has liquid level and clot detection for accurate pipetting. Liquid level detection is accomplished by capacitance measurement. Clot detection is accomplished by a pressure transducer.

Sample syringe

The sample syringe is located on the right behind the front door of the analytical module. The syringe is filled with deionized water and uses positive displacement to aspirate and dispense from the sample probe.

Incubator disk

The incubator disk contains 54 positions for AssayCups and is located approximately in the center of the analyzer unit. It is maintained at a temperature of 37.0 ±0.3 °C to ensure/facilitate reaction between the sample and the reagents that have been dispensed into an AssayCup.

When an assay is ready for measurement, the incubator rotates, moving the AssayCup to the various positions in the assay protocol process. The incubator transports each AssayCup to the position where the appropriate unit performs its respective task.

Sipper probes with rinse stations

There are two sipper probes located in front of the incubator (one probe for measuring cell 1 and the other probe for measuring cell 2). These aspirate the reaction mixture from the AssayCup in the incubator into the measuring cells as well as the ProCell and CleanCell from their respective cups in front of the sippers.

One rinse station for each sipper probe is located next to the sipper probes. The sipper probes move between measurements to their rinse stations and are washed externally with deionized water. In standby mode, the sipper probes are located directly above their rinse stations.

Sipper syringes

The sipper syringes are located on the right behind the front door of the analytical module. The pipetters are filled with deionized water and use positive displacement to aspirate and dispense from the sipper probes.

Measuring cell

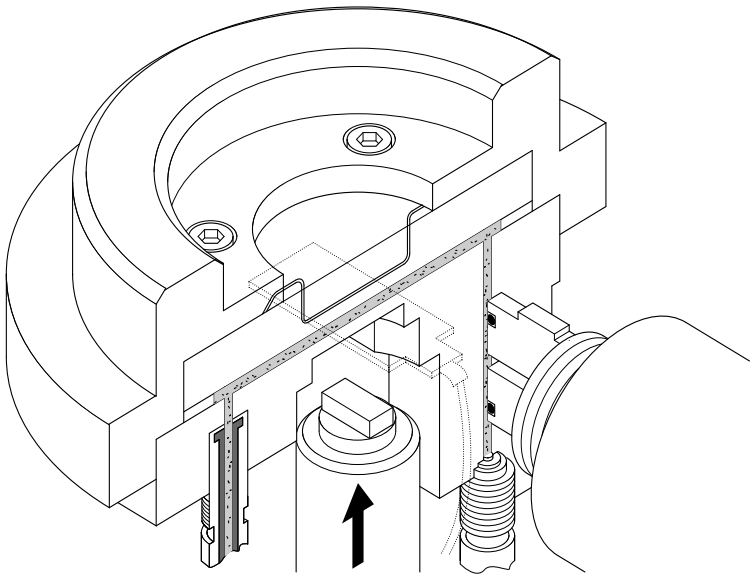


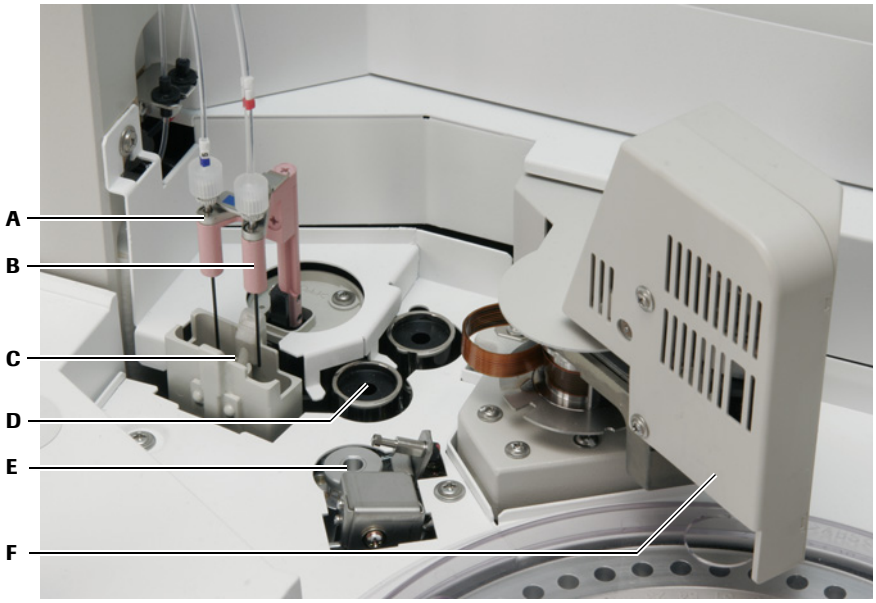
Figure A-50 Measuring Cell

The two measuring cells, which are located inside the analytical module, are the central components of the measuring cells of the **e** 601 module for the determination of samples. Each unit contains a photomultiplier tube, peltier, flow-through measuring cell, magnet drive assembly and an amplifier circuit board.

Pre-wash area components

The Pre-wash station is located in the middle at the back of the analytical module. It carries out a pre-wash step to remove interfering components from the reaction solution before the mixture goes into the measuring cell if defined in the assay protocol.

It consists of the following components:



A Dispenser
B Sipper
C Rinse station
D Separation stations
E Vortex mixing station
F Gripper

Figure A-51 Components of the Pre-wash area

Pre-wash gripper

The Pre-wash gripper is located at the back and on the left of the incubator and can move between the incubator and the Pre-wash area.

It is equipped with gripping fingers for gripping AssayCups which are filled with the reaction solution in the incubator and transporting them to the separation stations in the Pre-wash area and back. The gripper also transports the AssayCups from the separation stations to the vortex mixer.

Pre-wash sipper

The sipper is located at the back and on the left of the Pre-wash area, beside the dispenser. It aspirates the reaction solution from the AssayCup positioned in one of the separation stations.

Pre-wash dispenser

The dispenser is located at the back and on the left of the Pre-wash area, beside the sipper. It dispenses PreClean solution (a phosphate buffer) into the AssayCup after the sipper has drained the reaction solution.

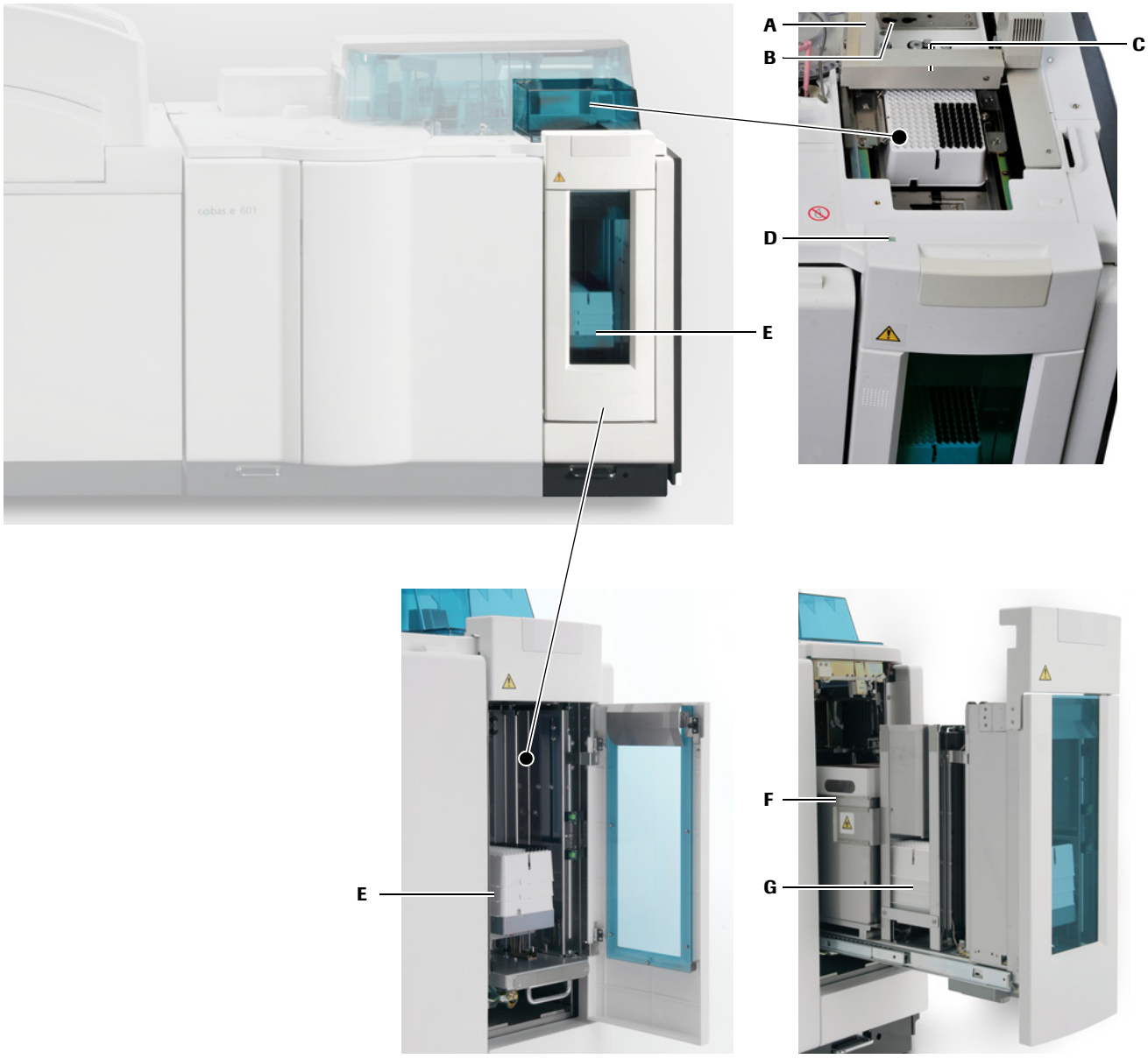
Rinse station The rinse station for sipper and dispenser probes is located beside the sipper and dispenser. It rinses the corresponding probe after each aspiration or dispensing procedure with deionized water.

Separation stations Two separation stations (AssayCup holders) are located in front of the sipper and dispenser, which are in the middle of the Pre-wash area. The separation stations are permanent magnets used to capture the microbeads in the AssayCup as the reaction solution is being aspirated by the sipper.

Vortex mixing station The vortex mixing station is located between the gripper and the separation stations. After the wash procedure, the AssayCup is positioned here by the gripper to resuspend microbeads in the PreClean solution.

Consumables area components

The components of the consumables are located on the right of the analytical module.



A Gripper
B Assay tip buffer station with disposal opening
C Vortex mixing station
D Indicator lamp
E Magazine lifter
F Solid waste containers
G Magazine waste compartment

Figure A-52 Consumables area components

Gripper

The gripper is located on the right of the analytical module and can move in 3 directions:

- X (left and right)
- Y (forward and back)
- Z (up and down)

It is equipped with gripping fingers for gripping tips or AssayCups. The gripping fingers grip an AssayCup from the magazine and transport it to the incubator or from the incubator to the vortex mixing station. After the AssayCup has been used, the gripper transports it to the cup disposal opening. The gripper also transports tips from the tip tray to the tip buffer where the sample probe picks them up for the next sampling.

During operation, the gripper is supplied with tips and AssayCups from the magazine lifter, which transports the magazines to the surface of the analytical module. Empty magazines are discarded automatically to the magazine waste inside the analytical module.

Vortex mixing station

The vortex mixing station, located between the gripper and the tip buffer, mixes the reaction solution after reagent delivery. AssayCups are transported here from the incubator by the gripper.

Assay tip buffer station with disposal openings

The AssayTip buffer station with disposal openings is located between the vortex mixing station and the sample probe. The gripper transports new tips here as required by the sample probe. The sample probe takes the new tip and, after pipetting samples, discards the used tip at the disposal opening into the active solid waste container.

AssayCup disposal openings

Used AssayCups are discarded by the gripper in the AssayCup disposal openings, located between the incubator and the vortex mixing station. The used cups pass into the active solid waste container.

AssayCup and tip magazine lifter

The magazine lifter is located behind the right front door of the analytical module and is the first compartment of the magazine drawer. It consists of the magazine lifter, the magazine waste, and the solid waste containers. The magazine lifter transports the full magazines to the surface of the analytical module as required. The lifter can be loaded with magazines by opening the transparent door of the magazine drawer. The magazines can be loaded on the magazine lifter only when the green indicator lamp is permanently illuminated.

Magazine waste compartment

The magazine waste compartment contains the empty magazines. It is located behind the right front of the analytical module and the middle part of a magazine drawer, which consists of the magazine lifter, the magazine waste, and the solid waste containers. The magazine waste can be emptied by pulling out the magazine drawer. The magazine drawer can be pulled out only when the green indicator lamp is permanently illuminated.

Solid waste containers

The solid waste containers are located behind the right front of the analytical module. They are the third compartment of a magazine drawer that consists of the magazine lifter, the magazine waste, and the solid waste containers. The 2 containers are used alternately. When one becomes full, the other becomes active. The full waste container can be emptied only when the green indicator lamp on the magazine drawer is permanently illuminated (i.e., the magazine drawer can be pulled out). The green button corresponding to the container should be pressed after the container has been emptied.

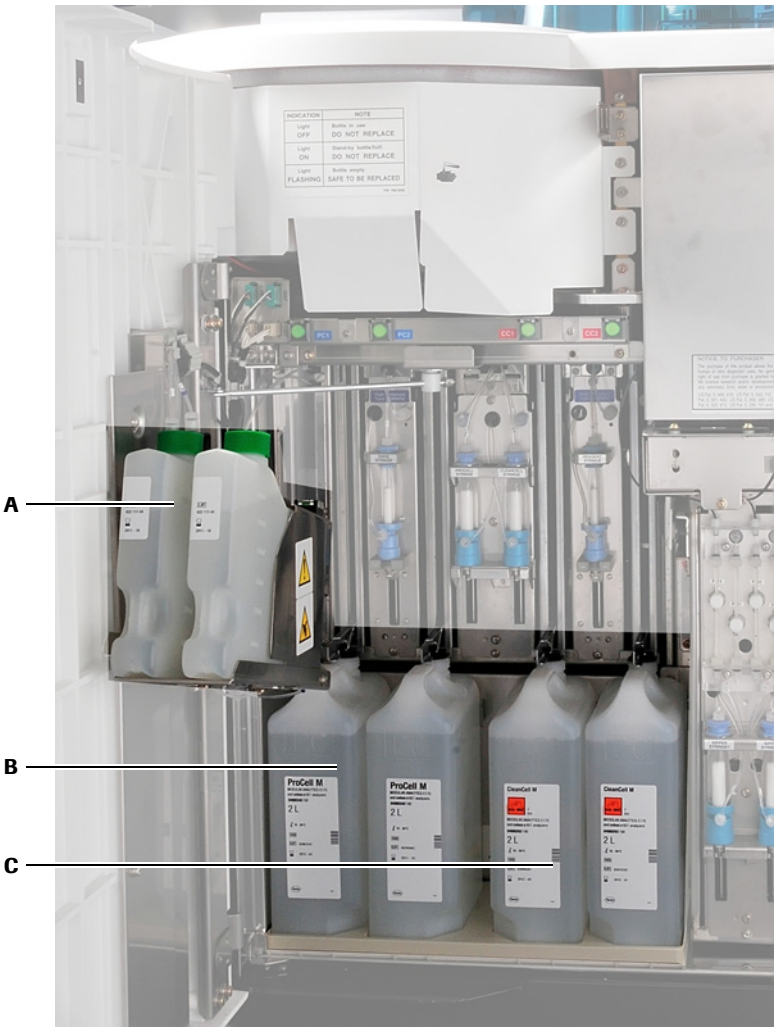
Green indicator lamp

The indicator lamp is located on the top of the right front door and indicates when the magazine drawer and door can be opened.

Green indicator lamp On	Drawer safe to open
Green indicator lamp flashing	About to operate—DO NOT open

Auxiliary reagents and cleaning solutions

The auxiliary reagent bottles of ProCell and CleanCell (two each) are located behind the front door of the e 601 module, and two bottles of PreClean are mounted on the inside of the door itself.



A PreClean bottles

B ProCell bottles (in keyed positions)

C CleanCell bottles (in keyed positions)

Figure A-53 Auxiliary reagents behind the front door

PreClean bottles

Two bottles of PreClean are located in the inner side of the front door of the module. Each bottle has a volume of 600 mL. Two bottles of each reagent allow bottle changeover without interrupting operation. The system monitors the amount of PreClean available by counting the number of pipetting actions. In addition, liquid short sensors are available in case of inaccurate counting due to incorrect loading of PreClean bottles.

See *Replacing empty PreClean* on page B-134.

ProCell and CleanCell bottles

Two bottles of ProCell and two bottles of CleanCell are located in special, keyed positions behind the front door:

- ProCell is a buffer solution containing tripropylamine (TPA). These bottles are identified with white caps and a special shape of the bottom of the bottle.
- CleanCell is a solution of potassium hydroxide (KOH) which is used to clean the measuring cell after measurement. CleanCell bottles are identified with black caps and a special shape of the bottom of the bottle.

The ProCell and CleanCell bottle positions are keyed to ensure the correct reagent is placed in the proper position. Each bottle has a volume of 2 liters and approximately two mL of each solution are needed for on determination. Two bottles of each reagent allow bottle changeover without interrupting operation.

See *Replacing ProCell and CleanCell when not empty* on page B-135.



If a ProCell bottle is replaced, the lot number of the new bottle must be entered into the system.

See *Status screen* on page E-259.

Specifications

This chapter gives an overview of the specifications of the **cobas** 6000 analyzer series and its modules.

In this chapter *Chapter* 6

General system specifications A-111
- Dimensions A-111
- Operating conditions A-112
- Environmental conditions A-113
- System interface A-113
- System start A-113
- Barcode types A-114
- Sample cups and tubes A-116
- Sample racks A-117

Control unit A-118
Core unit cu 150 A-118
c 501 module A-119
- Reaction system (c 501) A-119
- Sampling system (c 501) A-119
- Reagent system (c 501) A-120
- Photometric measuring system A-120
- ISE unit A-121

e 601 module A-122
- Reaction system (e 601) A-122
- Sampling system (e 601) A-122
- Reagent system (e 601) A-123
- ECL measuring system A-123

Table of contents

General system specifications

The following specifications apply to the **cobas** 6000 analyzer series.

Dimensions

Dimension	Module	International (Europe)	US
Depth	Max.	1040 mm	41.0 in
Height	**c** 501 module	1300 mm	51.2 in
	e 601 module	1140 mm	44.9 in
Length	rack sampler unit of **cu** 150	690 mm	27.2 in
	c 501 module	1200 mm	47.2 in
	e 601 module	1200 mm	47.2 in
Weight	**c** 501 module	330 kg	730 lb
	cu 150 incl. rack sampler unit and rack rotor	180 kg	400 lb
	e 601 module	360 kg	795 lb

Operating conditions

The power distribution panel and the water supply and drainage facilities must be available within 5 m of the system.

Water requirements

Bacteria-free, deionized water	< 10 cfu/mL
Conductivity	1.0 µS/cm or less
Water pressure	50-340 kPa
Water supply volume	• typical water consumption: • <c> system: 10 L/h • <e> system: 12 L/h • <cc> system: 20 L/h • <ce> system: 22 L/h • <ee> system: 24 L/h • <cce> system: 32 L/h • <cee> system: 34 L/h • max. water consumption per **c** 501 module: 40 L/h[(a)] • max. water consumption per **e** 601 module: 30 L/h[(a)]

(a) These max. water consumptions are theoretical values that may occur temporarily in service mode. Thus, the water supply of the laboratory must provide the max. water consumption of the system, for example 110 L/h for a <cce> system.

Electric power supply

Line voltage	Single phase AC 200/208/220/230/240V 50/60Hz
Power supply fluctuation	No significant power supply fluctuation (max. power supply change: ± 10%)
Overvoltage category	II
Pollution degree	2
Power consumption [(a)]	max. power consumption during Operation: • <c> system: 1.8 kVA • <e> system: 1.4 kVA • <cc> system: 2.6 kVA • <ce> system: 2.4 kVA • <ee> system: 2.6 kVA • <cce> system: 3.7 kVA • <cee> system: 3.6 kVA

(a) Power consumption is measured in one hour, at 25°C, and at AC 200V 50Hz.



The power supply must be grounded. The system can only be connected to a power supply source with the specified mains cable and only by authorized personnel.

Environmental conditions

The following environmental conditions should be followed in order to ensure correct operation of this system:

Ambient temperature	During operation: 18 to 32°C (64.4-89.6°F) with changes < ± 2°C/h (± 3.6°F⁄h) During transportation and storage: -20 to 75°C (-4 to 167°F)
Ambient humidity	During operation: 30-85% (non-condensing)[(a)] During transportation and storage: 5-95%
Altitude	< 2000 m
Electromagnetic interference	• No equipment generating electromagnetic waves in the near vicinity (e.g., cell phones, transceivers, cordless phones, etc.) • No machines discharging ultrahigh frequencies (e.g., electric discharger)
Noise levels	< 65 dB for surrounding
Other environmental conditions	• Dust-free environment with adequate ventilation • No direct sunlight • No perceptible vibration • Indoor use only
Floor condition	Level (angle: less than 1/200); strong enough to hold the weight of the instrument[(b)]

(a) Only valid for systems with appropriate hardware update.

(b) See *Dimensions* on page A-111.

System interface

The instrument can be bidirectionally interfaced with a Host.

System interface	RS-232C serial interface

All data processing equipment connected to the system must comply with the relevant standards of IEC, UL and CSA.

System start

System start-up time	12 min. (power on to standby) for a <ce> system

Barcode types

Barcodes used with the **cobas** 6000 analyzer series must be in compliance with one of the following standards:

- NW7 (Codabar)
- Code 39
- ITF
- Code 128

Sample barcodes

The following specifications apply to the various barcode types:

Reading method	Scanning with CCD sensor	
Used barcode symbol	NW7 (Codabar), Code 39, ITF, Code 128	
Check digit	Must be used to prevent scanning errors.	
Number of ID digits	NW7	3-13 digits + 1 digit (with check digit)
	Code 39	3-13 digits + 1 digit (with check digit)
	ITF	3-13 digits + 1 digit (with check digit)
	Code 128	4-12 digits + 2 digits (with check digit)
Characters usable for ID	NW7	0 to 9, -, /, ., $, :, + [(a)]
	Code 39	0 to 9, A to Z, -, ., [], /, +, $, %
	ITF	0 to 9
	Code 128	Alphanumeric (excluding those assigned to functions and communications)
Check digit	NW7	Modulus 16, Modulus 11, Modulus 10/2 weight, Modulus 10/3 weight, 7 check DR, weighted Modulus 11, Modulus 10/2 weight A
	Code 39	Modulus 43
	ITF	Modulus 10/3 weight

(a) For more information about usable characters and check digit characterization, refer to the common specifications for the different barcode types.

Sample rack barcodes

The following barcode types are used for sample racks:

Barcode, number of digits	ITF	5 digits + check digit

Scan range for sample barcodes

Confirm that the barcode zone starts at a minimum of 20 mm above the bottom of the tube. The barcode must be within the zone of 63 mm and must have a blank area of ≥ 5 mm at both ends of the barcode zone, as shown in the figure below. Stick the label in exact alignment with the centerline of the sample tube in order to prevent scanning errors.

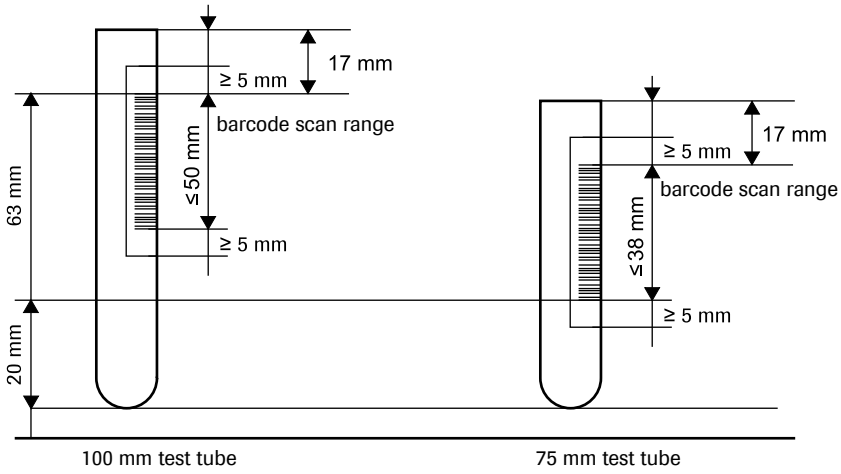


Figure A-54 Scan range of sample barcode reader

Sample cups and tubes

Container	Diameter × length	Comment	Dead volume
Primary sample tube	16 mm × 100 mm	Use for *cup on tube*	1000 µL
	16 mm × 75 mm	Use for *cup on tube*	1000 µL
Primary sample tube	13 mm × 100 mm		500 µL
	13 mm × 75 mm		500 µL
Hitachi standard cup directly on the sample rack or on top of a 16 mm diameter tube		2.5 mL	100 µL
Hitachi micro cup[(a)]		1.5 mL	50 µL
Calibrator/control vial[(b)]			200 µL
Non standard tube	12-16 mm × 73-102 mm	**c** 501	
	13-16 mm × 73-102 mm	**e** 601	
Roche Diagnostics Standard False Bottom Tube[(c)]	13 mm × 75 mm	**c** 501	100 µL
		e 601 with cup adapter	100 µL
Other false bottom tubes[(c)]	12-16 mm × 73-102 mm		

(a) Only to be used on **c** 501 modules. Not to be used for calibrators and controls.
If you use micro cups, you have to select micro cups on **Test Selection** screen as **Sample Cup**. Only in this case the dead volume for Hitachi micro cups is valid.

(b) Only to be used on the **e** 601modules.

(c) Only one type of false bottom tube (RD or other) is definable.

Cup on tube

Sample cups (both standard and micro cups) can be inserted into 16 millimeter sample tubes (cup on tube) or they can be used without tubes.

See *Sample containers* on page A-61.

Cup adapter

For the use of 13 mm tubes Roche Diagnostics requires use of cup adapters.

See *Correct placement of sample tubes on a rack* on page A-62.

Standard cups and micro cups

Standard cups and micro cups are too small to hold a barcode label, but it is possible to place them onto 16 mm sample tubes with a barcode label. Both cups can also be placed directly in a rack.

Use only cups certified by Roche Diagnostics. The following original standard cups are certified by Roche Diagnostics:

- Hitachi standard cup
- **cobas** sample cup (catalog no. 10394246001)

Sample racks

Rack type	Rack color	Display in software	Label on rack
Routine rack	Gray	N00001-N03999	001-3999
STAT rack	Red	E00001-E00999	S001-S999
Rerun rack[(a)]	Pink	R00001-R00999	R001-R999
Calibrator rack	Black	S00001-S00999	C001-C999
QC rack	White	C00001-C00999	Q001-Q999
Wash rack	Green	W00999	W999
MPA rack			

(a) Rerun racks are used for manual reruns in non-barcode mode only.

Control unit

Computer	Computer with Windows operating system
DVD drive	4.7 GB capacity Applicable data media DVD-R, DVD+R, DVD-RW, DVD+RW See *Preparing a DVD disk* on page B-244.
Monitor	17" TFT color monitor with touch screen system
Input devices	Mouse, touch screen, keyboard
Computer stand	Optional, ergonomic (UL, CE, GS, TÜV)

Data storage capacity

Sample data (routine/STAT)	10 000 samples (including reruns)	
Reaction process data	10 000 tests	
Calibration data	> 1000 tests	
Quality control data	Individual:	100 control materials, 2500 results per **c** module, 2500 results per ISE module, 2500 results per measuring cell (**e** module)
	Cumulative:	100 control materials, 500 points

Core unit cu 150

The following specifications apply to the rack sampler unit of the core unit **cu** 150.

Rack transfer	120 racks/h
Rack loader	30 racks (150 samples) (15 racks / tray + a buffer for 15 racks)
Rack unloader	30 racks (150 samples) (15 racks / tray + a buffer for 15 racks)
Rack rotor	20 positions, definable for STAT and auto QC
Rerun buffer	Up to 20 racks (100 samples) for automatic rerun possible
Reflex testing	Automatic reflex is supported by the system, reflex request to be provided by PSM or LIS

c 501 module

The following specifications apply to the **c** 501 module.

Reaction system (c 501)

Applications	Up to 131 applications: • 117 photometric applications can be registered • 3 electrolyte applications • 8 calculated tests • 3 serum indices
Number of simultaneous tests	Up to 60
Throughput	1000 tests/h (photometric and ISE)
Reaction volume	100-250 µL
Reaction temperature	37 ± 0.1°C (98.6 ± 0.2°F) circulating incubator bath
Reaction disk	Turntable system with 160 reaction cells
Reaction cells	8 segments of 20 reaction cells each (semi-disposable cuvettes for photometry)
Reaction times	3-10 min, in 1-minute steps
Pipetting cycle	6 s
Mixing method	Non-contact ultrasonic mixing

Processing capacity varies depending on measuring conditions, test selection and system configuration

Sampling system (c 501)

Sample types	Serum/plasma, whole blood, urine, CSF, supernatant (hemolysate)
Sample pipetting volume	1.5-35 µL, in 0.1 µL increments
Detection of sample blockages	Pressure sensitive clot detection system
Liquid level sensor	Capacitance sensing technology

For more information, see *Sample cups and tubes* on page A-116.

Reagent system (c 501)

Reagent identification	Automatic identification, automatic placement
Reagent pipetting volume	5-180 µL, in 1 µL increments (5-19 µL: + 20 µL water)
Reagent pipetting timing	3 timings possible (R1: 3.2 s; R2: 90.2 s; R3: 300.2 s)
Reagent storage	Refrigerated compartment for up to 60 reagent cassettes
Reagent bottles	4 different configurations available with up to 3 reagent bottles/cassette: • COBAS INTEGRA cassette: Pos. A: 22.6 mL, Pos. B/C: 11.0 mL • **cobas c** pack: bottles of 20 mL, 40 mL, or 60 mL: (20/40/20 ml, 40/40 ml, 60/20 ml)
Reagent cooling	5-12°C (41-53.6°F)
Remaining reagent volume control	Automatic test countdown with each pipetting
Capacity of cassette disposal	10 reagent cassettes

Photometric measuring system

Light source	Halogen lamp, 12 V / 50 W
Photometer	Multiple wavelength spectrophotometer
Wavelengths	12 wavelengths available: 340, 376, 415, 450, 480, 505, 546, 570, 600, 660, 700, 800 nm
Optical path length	5.6 mm
Optical range	0.0000-3.3000 absorbance
Linearity	Up to 2.5 absorbance
Optical mode	Monochromatic and bichromatic

ISE unit

Applications	Na^+, K^+, Cl^- in serum and urine	
Detection system	Ion-selective electrode system	
Throughput	200 samples/h (corresponding to 600 tests/h)	
Sample pipetting volume	9.7 µL	(normal sample volume)
	6.5 µL	(decreased sample volume for urine, manual rerun only)
Reagent pipetting volume	Dil	348 µL/sample (291 µL is dispensed into the cuvette to get a dilution to 1/31)
	ISE IS	590 µL/sample (measurements in succession) 1180 µL/sample (single measurement)
	KCl	130 µL/sample
Measuring range (serum)	Na^+	80-180 mmol/L
	K^+	1.5-10.0 mmol/L
	Cl^-	60-140 mmol/L
Measuring range (urine)	Na^+	20-250 mmol/L
	K^+	3-100 mmol/L
	Cl^-	20-250 mmol/L
Measuring temperature	37° ± 2°C (98.6° ± 3.6°F)	
	(during operation ± 0.5°C/0.9°F)	
Cycle time	18 s	
Liquid level sensor	Capacitance sensing technology	
Mixing method	Non-contact ultrasonic mixing	

e 601 module

The following specifications apply to the **e** 601 module:

Reaction system (e 601)

Applications	max. 60 heterogeneous immunoassays assays can be installed
Test principals	Competitive tests, sandwich tests and bridging tests
Reaction volume/test	Nominal: approx. 200 µL Real: approx. 160 µL
Throughput	Up to 170 tests/h
Reaction disk	54 positions
	Carryover-free reaction as AssayCups are used only once
Incubator temperature	37 ± 0.3°C (98.6 ± 0.5°F)
Reaction times	9, 18 and 27 min assays
Cycle time	21 s per module, 42 s per channel
Mixing method	Non-invasive vortex mixers

Sampling system (e 601)

Sample types	Serum, plasma, urine
Sample pipetter principle	Conductive disposable tip handling
	Carryover-free pipetting as AssayTips only used once
Sample pipetting volume	Nominal: 10-50 µL
	Real: 8-40 µL
Sample detection	Liquid level detection (LLD) and clot detection
AssayTips	84 tips / magazine
AssayCups	84 cups / magazine
Magazine loading capacity	Up to 12 loaded magazines are possible with 1008 AssayCups and 1008 AssayTips

For more information, see *Sample cups and tubes* on page A-116.

Reagent system (e 601)

Reagent disk temperature	20 ± 3°C (68 ± 5.4°F)
Reagent disk capacity	25 **cobas e** packs in 25 positions
Reagent pipetting volume	Nominal: 40-64 µL/test dependent upon the assay
Microbead consumption	Nominal: 24-40 µL/test dependent upon the assay
ProCell consumption	≤ 2.0 mL/cycle
CleanCell consumption	≤ 2.0 mL/cycle
PreClean consumption	≤ 550 µl/Pre-wash
Reagent volume control	Liquid level detection (LLD)
Positive reagent identification	2-dimensional barcode (PDF417)
Automatic dilution	Available
Evaporation protection	Reagents are automatically opened and closed
Inventory control	Available

*Waste handling (**e** 601)*

Liquid waste handling	Optional: Two waste containers (20 L)
Solid waste handling	Two waste boxes for used AssayTips and AssayCups (max. 672 per box) and the magazine waste section for magazine waste (max. 12 magazines).

ECL measuring system

Measuring method	Integral measuring of an electrochemiluminescence (ECL) signal
Measuring cells	2 individually calibrated ECL measuring cells
Calibration mode	two-point calibration
Auxiliary reagents temperature	28° ± 2°C (82.4 ± 4°F)
Measuring unit temperature	28° ± 0.3°C (82.4 ± 0.5°F)
Pre-wash station temperature	20° ± 1°C (68 ± 2°F)

e 601 module

Operation B

7 Software basics B-3
8 Daily operation B-27
9 Orders and results B-77
10 Reagents B-103
11 Calibration B-153
12 QC B-195
13 Extended operation B-231
14 Configuration B-249

Software basics

This chapter is an introduction to the basic operational procedures for the **cobas** 6000 analyzer series.

In this chapter *Chapter* 7

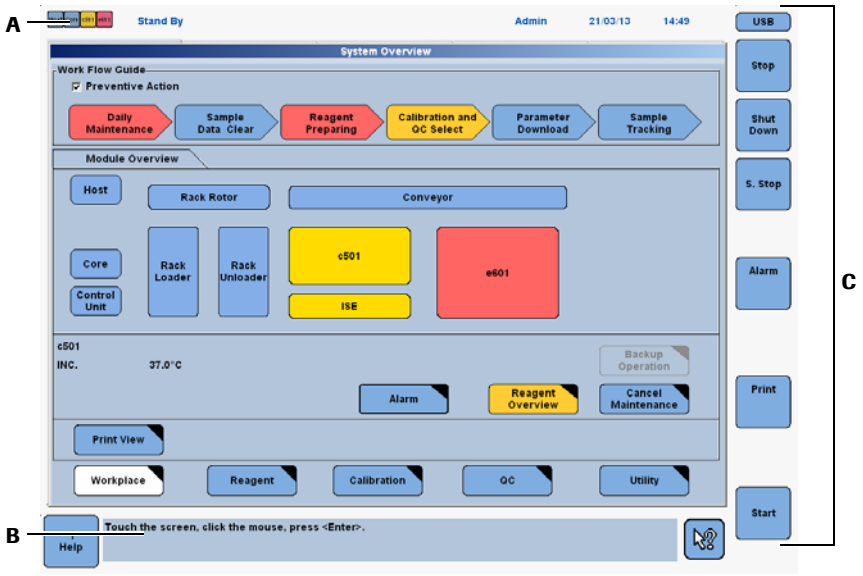
General description of the user interface B-5
Status line B-6
Guidance prompt B-6
Menu tabs B-7
List boxes B-7
Text boxes B-7
Options B-8
Check boxes B-8
Buttons B-8
Standard buttons B-9
Global buttons B-10
Windows B-10
Screen accessibility B-10
Shortcut Keys B-11
The help system of the instrument B-13
About F1 Help B-13
The F1 Help window B-14
Button bar B-14
Navigation pane B-15
Topic area B-16
Searching for information in the help system B-16
Search options and recommendations B-18
Using favorites B-19
Printing F1 Help topics B-20
About Direct Help B-20

Main menus B-21
System Overview B-21
Workplace B-22
Reagent B-23
Calibration B-24
QC B-25
Utility B-26

General description of the user interface

The screen representations shown in this chapter and throughout this manual are for illustrative purposes only. The screens do not necessarily show valid results.

The screen of the PC is divided into different sections. Some of these sections do not change and some differ according to the currently active function. Following is an example of a screen showing the different areas.



A Status line
B Guidance prompt
C Global buttons

Figure B-1 Screen configuration

Status line

The status line appears across the top of each screen.



Figure B-2 Status line

The status line displays the current operational mode, operator ID, date and time, and the time remaining when performing maintenance. The icon on the left displays the current statuses of the system modules. Touching this icon displays the **System Overview** screen with information of the selected item/module.

The following describes the colors from the lowest to the highest priority:

- Light green indicates standby mode.
- Light blue indicates statuses other than standby (for example, maintenance).
- Purple indicates that the number of tests remaining for a reagent or a reagent volume is less than the Purple alarm level specified on the **Utility** > **System** (Page 2/4) > **Reagent Level Check** window.
- Pink indicates reload possibility (reagent reloading function of **e** 601).
- Yellow indicates an instrument alarm with a caution level or the number of tests remaining for a reagent is less than the yellow alarm level specified on the **Reagent Level Check** window.
- Red indicates an instrument alarm of **Stop**, **S.Stop** or **E.Stop** or the number of tests for a reagent is zero.
- Dark green indicates that a module has been inactivated on the **Utility** > **Module Set** > **Module Setting** window.
- Black indicates the module is powered off.
- An “X” on the module indicates the module is masked on the **Start Conditions** > **Masking** > **Module Masking** window.
- A "\" on the module indicates the module is service masked.

Guidance prompt

The guidance prompt is shown in the lower left of each screen.



Figure B-3 Guidance prompt

In this area, the software prompts you as to what kind of information to type and what format to use when typing that information. The guidance prompt may also tell what action to take, such as touching a button or pressing a key. For example, “Touch screen or press <Enter>”. Each prompt is specific to the location of the cursor.

Menu tabs

The menu tabs are displayed below the status line.

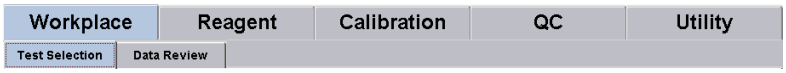


Figure B-4 Menu tabs

The menu tabs are used to select screens and windows that are grouped together and perform related tasks. The menu tabs are accessible from every screen, except the global screens. This makes the software navigation within the menus and between menus very easy.

The menu tabs are only for the 5 menus: **Workplace**, **Reagent**, **Calibration**, **QC** and **Utility**. The menu tabs can be selected by touchscreen, mouse or keyboard.

List boxes

List boxes display a list of choices. If there are more choices than can fit in the box, a scroll bar is displayed.

1. Touchscreen: Touch the desired area within the list box on the screen. If a scroll bar is displayed next to the list box, touch the scroll bar above or below the current display position, or touch the arrows on the scroll bar to move up or down the list.
2. Keyboard: The <Arrow> keys can be used to move quickly through the list. Press the <Arrow> key that points in the direction you want to move. The currently selected choice is indicated by the selection cursor, which appears as a highlight. The Home, End, Page Up and Page Down keys can also be used to move through the list. When the desired item is highlighted, press <Enter>.

Text boxes

Text boxes are used to type information. When you move to an empty text box, the box is highlighted.

1. Touchscreen: Move to a text box by touching it on the screen. The text box highlights when you touch it.
2. Keyboard: Move to a text box by pressing the <Tab> key. The text box highlights when you move to it.

Press the <Enter> key to accept information typed. The cursor then moves to the next field.

Options

Options are used to select a particular function. Sometimes when an option is selected, other fields become available.

An option is selected when a black circle is displayed within the white circle for the option. Only one option can be selected at a time.

1. Touchscreen: Move to the option by touching it on the screen. The option displays a black circle within the white circle when you touch the option.
2. Keyboard: Move to the option by pressing the <Tab> key or press the letter which is underlined. If multiple options are available, the up and down arrow keys move to the different options.

Check boxes

Check boxes are used to select a particular function. Sometimes when an option is selected, additional fields become available. Multiple check boxes can be selected in the same area of the screen.

1. Touchscreen: Move to the check box by touching it on the screen. A check mark appears in the check box when it is selected. When the check box is blank, it is not selected.
2. Keyboard: Move to the check box by pressing the <Tab> key or press the letter which is underlined. If multiple check boxes are available, the up and down arrow keys move to the different check boxes.

Buttons

Buttons are used for execution of functions, confirmation of entries and selections, and displaying pop-up windows. The available buttons depend on the menu or tab that is active. For example, the **Demographics** button on the **Workplace** > **Test Selection** screen displays a window that is used for the entry of demographic patient information.

The black triangle in the upper right-hand corner of a button indicates that touching this button displays another window. The black triangle in the lower left corner of a button indicates that touching this button performs the specified function and closes the window.

If a button is shaded, the button is not available in the current mode.

1. Touchscreen: Choose a button by touching it on the screen.
2. Keyboard: Press the <Arrow> keys, <Tab> key or press the letter which is underlined to highlight a button. Press the <Enter> key to initiate the action.

 In addition, each software button on screen or window has an action key: the letter underlined in the button name (e.g., the action key for "OK" is O). While pressing the <Alt> key, press the letter key corresponding to the button to activate the button.

Standard buttons

The following buttons are used throughout the software. These buttons are explained below and will not be explained again with each individual screen.

OK Touch this button to accept the changes and entries made on a window and to close the window.

Cancel Touch this button to close the window without saving the changes and entries made on a window

Yes Touch this button to accept the changes made on a window, execute the action of the window (e.g., Delete) and close the window.

No Touch this button to close the window without saving the changes made on a window or without executing the function of the window (e.g., Delete).

Close Touch this button to close the window.

Save When changes have been made, this button turns yellow. Touch this button to save any changes made to the screen/window currently displayed.

Update When changes have been made, this button turns yellow. Touch this button to update any changes made to the screen/window currently displayed.

Execute Touch this button to accept the changes made on a window, to execute the action of the window and to close the window.

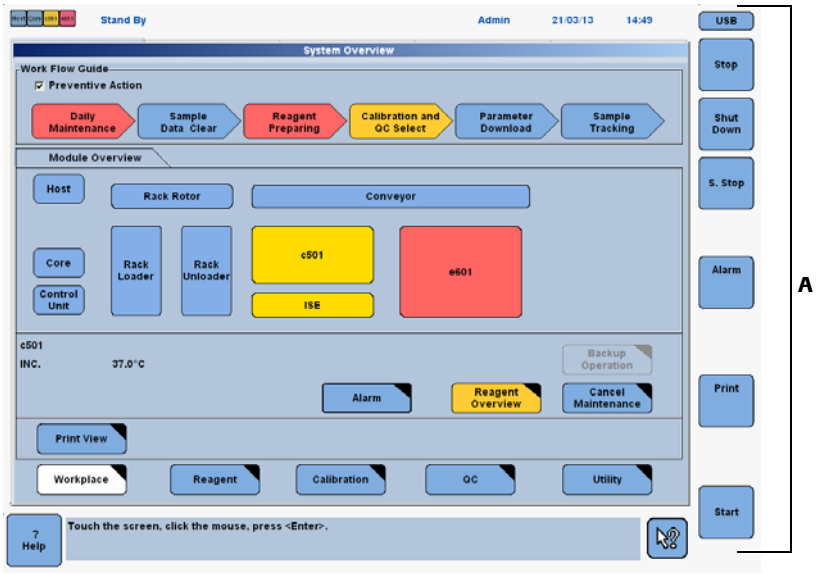
Page buttons The **Utility** > **System** screen displays page buttons that can be used to display additional buttons to display new screens. These page buttons are numbered (X/4), to indicate which page you are on.



The page buttons only change the displayed buttons and not the entire appearance of the screen.

Global buttons

Use the global buttons to display screens that are used for specific functions. The global buttons are accessible from every screen and appear on the right side of the screen (except for the **Help** button which appears on in the lower left corner of the screen). The global buttons include: **USB**, **Stop**, **Shut down**, **S. Stop**, **Alarm**, **Print**, **Start** and **Help**. The **Stop, S. Stop** and **Start** buttons are also the system control buttons. The global buttons can be selected by touchscreen, mouse or keyboard.



A Global buttons

Figure B-5 Global buttons

Windows

Windows contain additional information that pops up over existing screens/windows.

Windows function similar to screens. Information on a window can be entered or edited through list boxes, text boxes, options and check boxes. Action buttons are also available.

Confirmation window

Many functions require confirmation prior to their execution (e.g., **Delete**).

Confirmation windows are used to confirm these functions. Touch **Yes** to confirm the function and to close the confirmation window, or touch **No** to close the confirmation window without carrying out the function.

Screen accessibility

Some screens are not accessible with the operator level logon, or can be viewed with a supervisor level logon but not edited. Some fields are viewed only at the administrator level logon.

Shortcut Keys

All functions can be initiated via the keyboard or the touchscreen for selection of screen items.

All special keys and their functions are described below.

Shortcut	Description
<F1>	Use this key to display the Online Help.
<F2>	Use this key to display the **Start Conditions** screen.
<F3>	Use this key to display the **Sample Stop** screen.
<F4>	Use this key to display the **Stop** screen.
<F5>	Use this key to display the **Workplace** menu. This key does not work if you are in a global screen.
<F6>	Use this key to display the **Reagent** menu. This key does not work if you are in a global screen.
<F7>	Use this key to display the **Calibration** menu. This key does not work if you are in a global screen.
<F8>	Use this key to display the **QC** menu. This key does not work if you are in a global screen.
<F9>	Use this key to display the **Utility** menu. This key does not work if you are in a global screen.
<F11>	Use this key to display the **Alarm** screen.
<F12>	Use this key to display the **System Overview** screen.
<Print/Print Screen>	Use this key to display the **Print** screen. Press <Shift + Print Screen> simultaneously to print the current screen.
<Scroll Lock>	Use this key to display the **Cancel Print** window.
<Pause/Break>	Use this key to display the **Logoff** screen.
<Esc>	Use this key to exit a window or global screen.
<Tab>	Use this key to move to the next field in a window or screen. To go from a field to the previous one, press <Shift + Tab> simultaneously.
<Enter>	Use this key to confirm an entry.
<Shift>	Simultaneously pressing <Shift> and a character key generates a capital letter or a special character, for example <Shift> + <, generates the character ">".
<Backspace>	Use this key to delete a character to the left of the cursor.
<Space>	Use this key to generate a space.

Table B-1 Shortcut Keys (Sheet 1 of 2)

Shortcut	Description
<Delete>	Use this key to delete a character to the right of the cursor.
<Home>	Use this key to place the cursor at the beginning of a list or text box.
<End>	Use this key to place the cursor at the end of a list.
<Page Up>	Use this key to scroll upward in a list, one page at a time.
<Page Down>	Use this key to scroll downward in a list, one page at a time.
<Arrow>	Use these keys to move the cursor to the right, left, upwards or downwards within a text box.
<Caps Lock>	Use this key to lock the letter keys into the upper case mode.
<Num Lock>	Use the numerical key pad for entry of numbers and mathematical operators such as +, -, /, *.

Table B-1 Shortcut Keys (Sheet 2 of 2)

The help system of the instrument

The user interface of the **cobas** 6000 instrument has a context-sensitive online help system to support you in operating the instrument.

Context-sensitive means that the help system always displays information related to the current screen or software element. Therefore, the help system offers a quick and convenient way to find information.

The instrument software offers two help features:

- F1 Help
- Direct Help (tooltips)



A F1 Help button **B** Direct Help button

Figure B-6 Online help buttons

For more information on the help system, see:
About F1 Help on page B-13
Searching for information in the help system on page B-16
Printing F1 Help topics on page B-20
About Direct Help on page B-20

About F1 Help



The **F1 Help** feature displays information related to the current screen. Hypertext links guide you to additional information and procedures related to this screen.

The name F1 Help results from the fact that this help is also available by pressing the F1 key.

Operator's Manual included in the F1 Help system

The Operator's Manual is included in the F1 Help system. This allows you to search for information throughout the software reference and the manual. All cross-references are implemented as hyperlinks.

► To display the F1 Help feature for the current screen

1 Open the screen or window for which you want detailed information.

2 Choose the **Help** button in the bottom left corner of the screen or press <F1> on the keyboard.

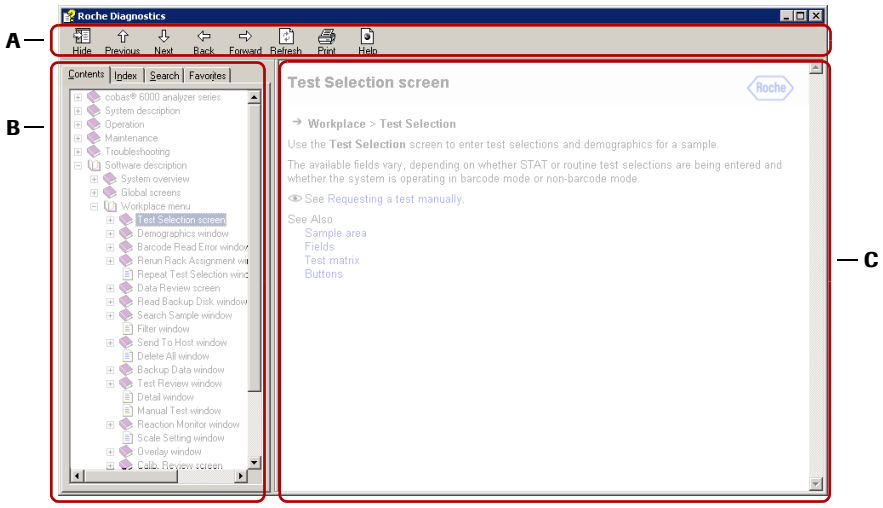
The **cobas** 6000 help opens displaying the desired help information.

■

The F1 Help window

The F1 Help window comprises three main areas:

- Button bar
- Navigation pane
- Topic area

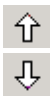


A Button bar
B Navigation pane
C Topic area

Figure B-7 Areas of the F1 Help window (example screenshot from the English version)

Button bar

The buttons at the top of the help window provide the following functions:

Hide/Show		Allows you to show or hide the navigation pane. This feature provides more space in the topics pane, which may be desired for displaying large figures.
Previous/Next		Use these buttons to open the topic above or below the current topic. If there is no topic to view above, the **Previous** button is unavailable.
Back/Forward		Use these buttons to backtrack through the topics you have previously reviewed, in the order in which you viewed them. The record of topics viewed is deleted each time you exit the F1 Help.
Refresh		This is a standard function of Internet browsers for refreshing the screen. You do not need this button for displaying F1 Help.
Print		Prints the topic currently displayed in the topic area.
Help		Directs you to information about the help system (*help on help*).

Navigation pane

The navigation pane appears to the left of the help window. There are four tabs available at the top of the pane: **Contents**, **Index**, **Search**, and **Favorites**.

- The **Contents** tab uses book and page symbols to display the contents of the F1 Help and remains synchronized with the topic displayed in the topic area.
- The **Index** tab provides access to the help index.
- The **Search** tab provides access to a full-text search feature.
- The **Favorites** tab allows organizing important topics with your personal bookmarks.

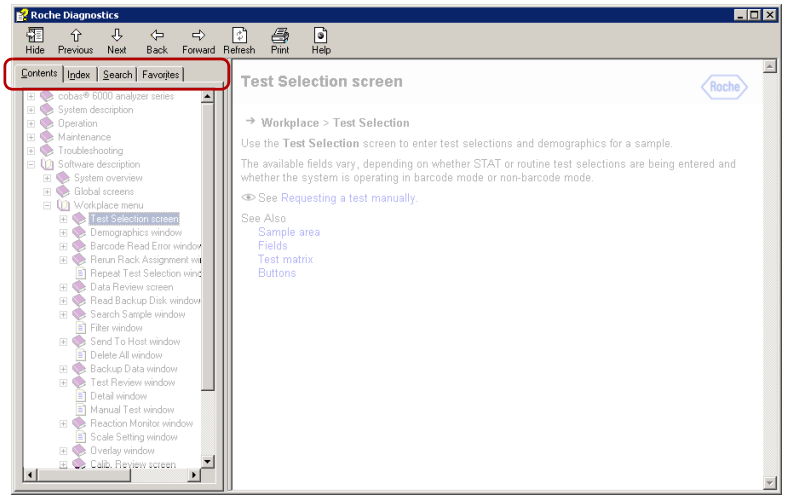


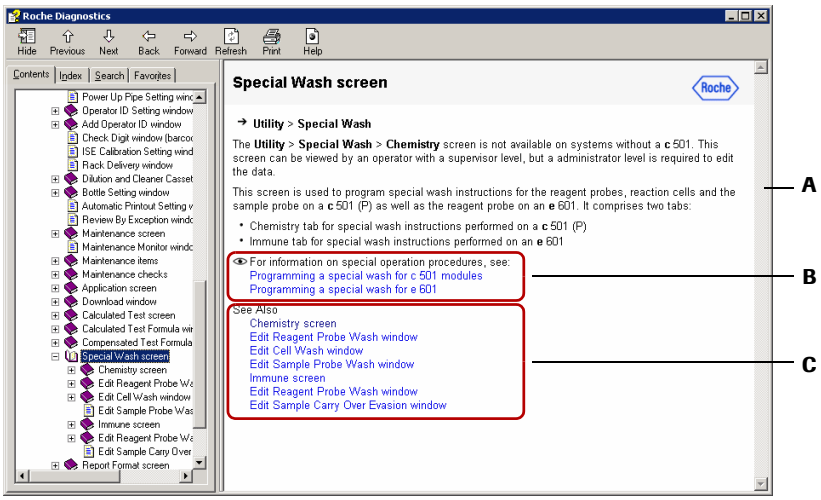
Figure B-8 The tabs in the Navigation pane

For information on the **Contents**, **Index**, **Search**, and **Favorites** tabs, see:
Searching for information in the help system on page B-16
Using favorites on page B-19

Topic area

Help topics appear in the area to the right of the navigation pane. The topic area comprises the description related to the topic selected in the navigation pane.

If the topic extends beyond the window, scrollbars allow you to view the rest of the topic.



A Scrollbar (if necessary)

B Links

C Related topics at the end of the topic

Figure B-9 Topic area (example screenshot from the English version)

Related topics At the end of a topic, all subtopics to the current topic are listed.

Alternatively, you can navigate to subtopics using the **Next** button or using the **Contents** tab.

Links Cross-references to associated topics are indicated by blue text. When you hover over a link, the mouse pointer changes to a hand icon.

For information on the symbols used in the topic area, see *Conventions used in this manual* on page 11.

Searching for information in the help system

There are various methods of finding the desired information in the F1 Help. Select your preferred method.

- The **Contents** tab displays the structure and contents of the **cobas** 6000 help system allowing you to navigate to the desired location.
- The **Index** tab displays a list of predefined keywords based on the topic titles and words or phrases in the help system.
- The **Search** tab allows you to perform a full-text search in the help system.

► To use the Contents tab

1 Choose the **Help** icon in the lower left corner of the screen or press <F1>.

The **Help** window displays information related to the current screen of the user interface.

2 If you require information about another topic, use the navigation pane on the left:

- Double-click on a book symbol to further expand the contents structure (or click on the plus symbol). The structure in the navigation pane expands showing the available topics.
- Click on a book symbol or a page symbol to display the corresponding topic.
- Use the scrollbar of the navigation pane to scroll up and down within the topics of the help system.

■

► To use the Index tab

1 Choose the **Help** icon in the lower left corner of the screen or press <F1>.

The **Help** window is displays information related to the current screen of the user interface.

2 Choose the **Index** tab to display the list of index entries.

3 Type the desired index entry or scroll through the index list. As soon as you start typing the index entry, the entries that most closely match the text that you type are displayed in the index list.

4 When you have found the desired index entry, double-click the entry or select the entry followed by **Display** to display the topic in the topic area.

■

► To use the Search tab

1 Choose the **Help** icon in the lower left corner of the screen or press <F1>.

The **Help** window is displays information related to the current screen of the user interface.

2 Choose the **Search** tab.

3 In the text box, type the search term(s) you want to find.

4 Choose the **List Topics** button to show the search results.

5 The bottom list displays the titles of topics that match the search term(s).

6 Double-click a topic title to display this topic in the topic area.

Or: Select the topic title and choose the **Display** button.

👁 See *Search options and recommendations* on page B-18.

■

Search options and recommendations

Recommendations for better search results

The number of search results is displayed above the result list (**Found: xx**).

Problem	Recommendation
Too many search results	1. Select the **Search titles only** check box. 2. Deselect the **Match similar words** check box. 3. Select the **Search previous results** check box and enter a new search term(s) that is associated with your desired information. 4. Connect two or more search terms with **AND**, **OR**, **NEAR**, or **NOT** (see arrow button on the right of the text box).
The desired information is not contained in the search results	1. Select the **Match similar words** check box. 2. Deselect the **Search previous results** and the **Search titles only** check boxes. 3. Maybe you are using terms that are different from the terms used in the help system. Use the **Index** tab for your search.

Table B-2 Recommendations

Search options

The following table describes the search options in the F1 Help:

Search option	Explanation
AND	Use this option to join words or phrases when both (or all) terms must appear in the search results.
OR	Use this option to join synonymous or related terms when either (or both) of the terms must appear in the search results.
NEAR	Use this option to find words within 10 words of each other.
NOT	Use this option to exclude a particular word or combination of words from your search results.
Search previous results	Select this check box to limit the search results and search through your results list from previous search. Deselect this check box if you want to search through all of the files in the Online Help.
Match similar words	Select this check box to find similar words and minor grammatical variations for the phrase you search.
Search titles only	Select this check box to search titles only. Deselect this check box for a full text search.

Table B-3 Search options

Using favorites

You can add a favorite, also called bookmark, to Online Help topics that you want to visit again. The favorites work similar to the favorites in your web browser.

► To add a favorite

1 In the F1 Help, search for or navigate to the desired topic.



Figure B-10 **Favorites** tab (example screenshot from the English version)

2 Choose the **Favorites** tab to display the list of favorites.

The topic title is displayed in the **Current Topic** text box.

3 To rename the topic, enter another name.

4 Choose the **Add** button. The new favorite is inserted in alphanumeric order.

Any time you want to open that topic again, choose the **Favorites** tab and then select it from the **Topics** list.

Organizing favorites by prefixes

To organize a number of favorites, we recommend using a numeric prefix at least for each main menu (e.g., 1 = **Workplace**, 2 = **Reagent**, …). All topics from the **Workplace** menu will then appear together under the prefix 1.

■

► To rename a favorite

1 In the **Favorites** tab, select the desired favorite.

2 Right-click on the favorite name and select **Rename**.

3 Type the new name and press <Enter>.

■

Printing F1 Help topics

You may find it useful to print a topic from the **cobas** 6000 Online Help.

► **To print a help topic**

1 In the F1 Help, search for or navigate to the desired topic.

2 To print the current topic, choose the **Print** button.

3 Check the printer settings and choose **Print** to print the selected topic.

■

About Direct Help



The **Direct Help** feature displays brief information related to a single software element, such as a button or field. Use this help feature if you only require a tooltip about an element.



The Direct Help can only provide short tooltips

If you require more information about an element, please press <F1> to open the F1 Help system.

► **To call-up the Direct Help feature for a single element**

1 Touch (or click) the **Direct Help** icon in the bottom right corner of the screen.

2 Wait until a question mark (?) is displayed next to the pointer.

3 Touch the screen element for which you want detailed information. A tooltip (pop-up window) is displayed containing information about this screen element.

4 Touch any part of the screen to close the pop-up.

■

Main menus

The graphical user interface used by the control unit consists of 6 main screens, **System Overview**, **Workplace**, **Reagent**, **Calibration**, **QC** and **Utility**, and 6 global screens. Through these screens all instrument functions are controlled.

Access to some screens, especially those of the **Utility** menu, is confined to the access level of the user. For this reason, the screen may not appear exactly as shown here.

See *Overview of access levels* on page E-403.

System Overview

The **System Overview** screen has a central role within the **cobas** 6000 software. From here the user has an overview of the whole system at any given time. It displays the status of each module, and the modules can be prepared for daily routine operation.

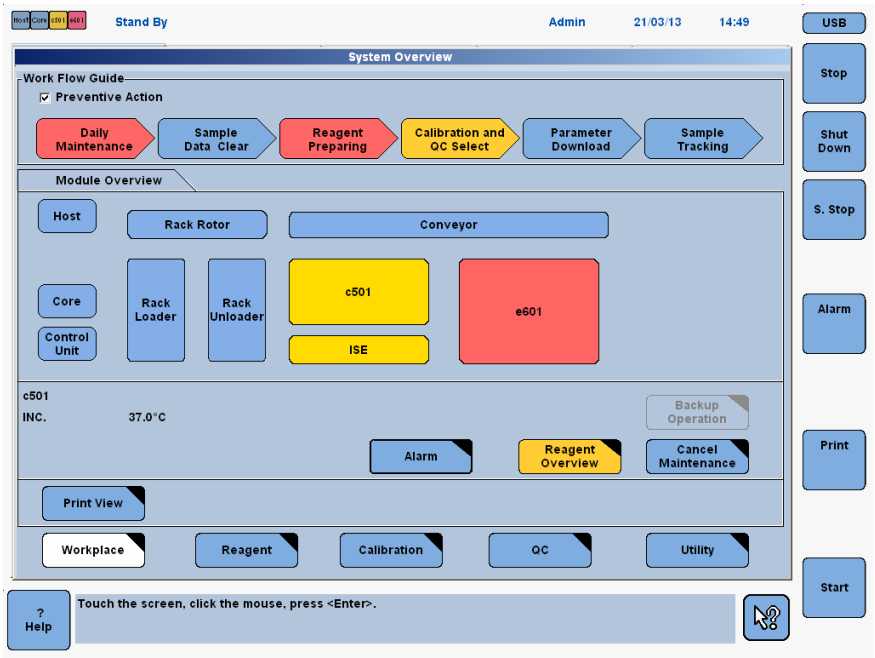


Figure B-11 System Overview screen

For more information, see *System Overview screen* on page B-35.

Workplace

The **Workplace** menu consists of three screens: **Test Selection**, **Data Review** and **Calib Review**. Use the **Test Selection** screen to make test selections, specify patient demographics, and assign patient IDs and rack positions to samples. Use the **Data Review** screen to review, backup, edit, delete and send data to the Host. Use the **Calib Review** screen to review the status of the calibrators that are currently processing and the status of the calibrations.

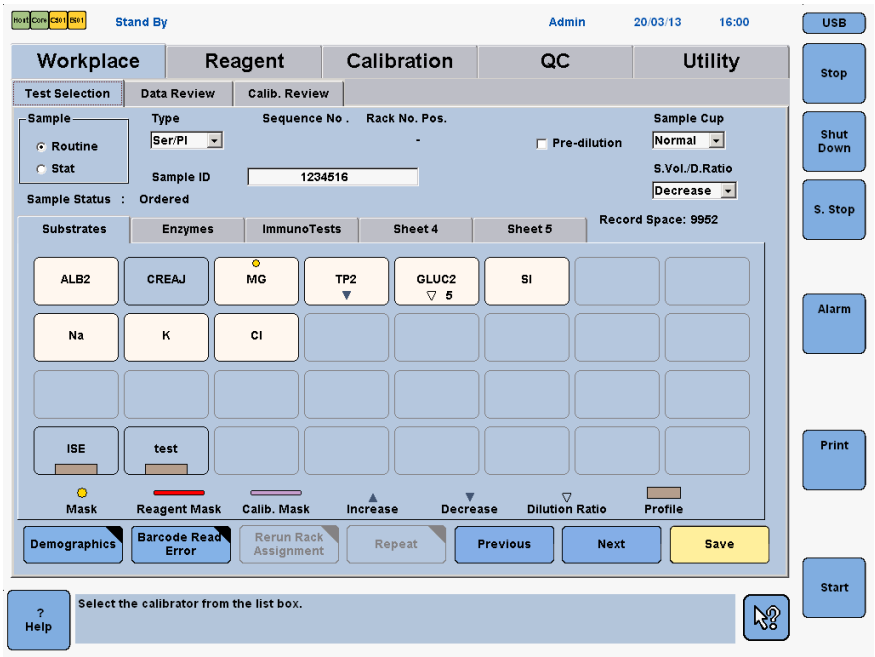


Figure B-12 Workplace menu

For more information, see:
Test Selection screen on page B-80
Data Review screen on page B-88
Calib. Review screen on page B-96

Reagent

The **Reagent** menu consists of two screens: **Setting** and **Status**. These screens are used to view detailed reagent information and to perform operation related to reagent management.

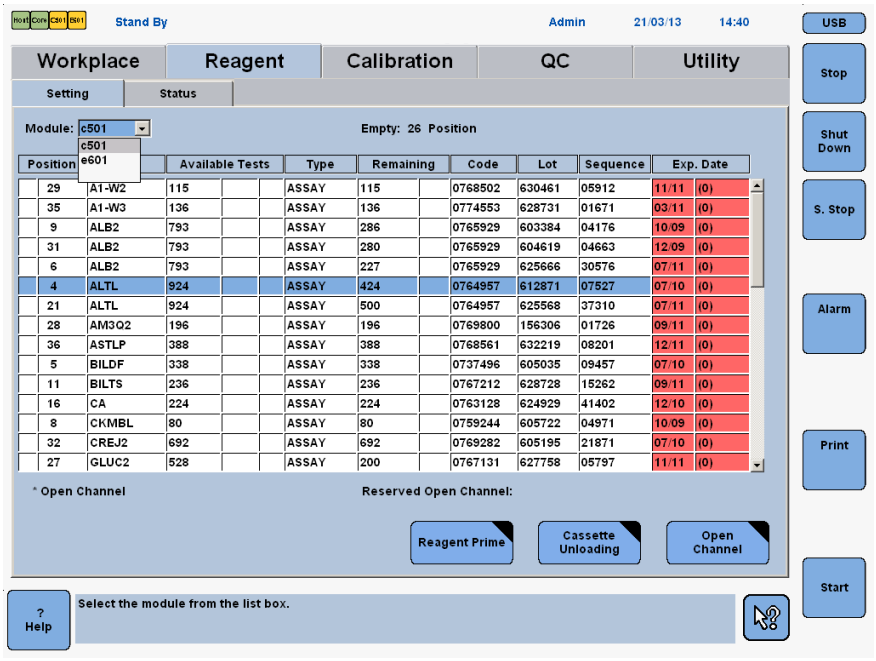


Figure B-13 Reagent menu

For more information, see:
Reagent Setting screen on page B-125
Reagent Status screen on page B-130

Calibration

The **Calibration** menu consists of three screens: **Status**, **Calibrator** and **Install**. These screens are used to request calibrations, define calibrators and view the reaction curves for calibrators installed on the system.

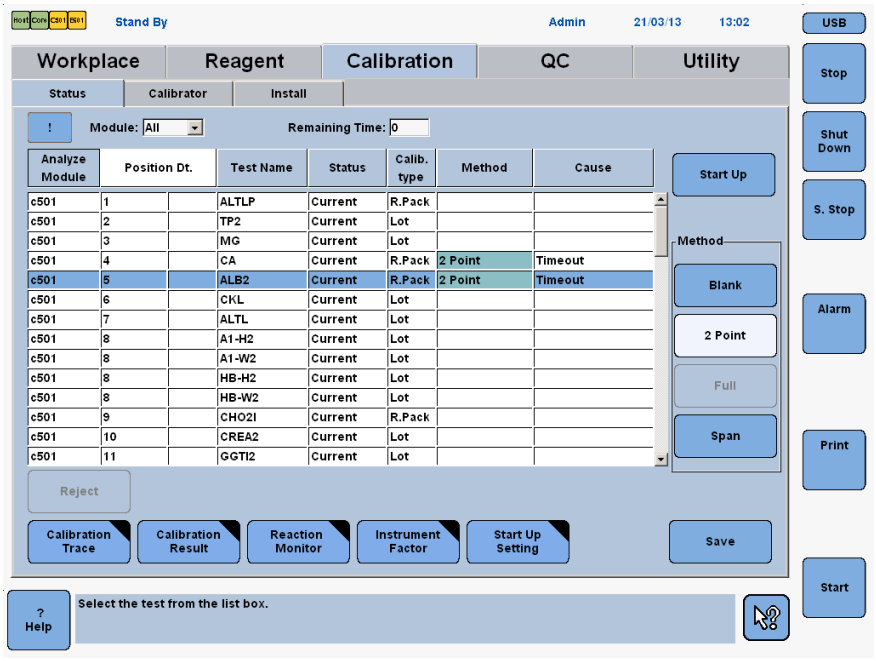


Figure B-14 Calibration menu

For more information, see:
Calibration Status screen on page B-166
Calibration Install screen on page B-181
Calibration Calibrator screen on page B-178

QC

The **QC** menu consists of 6 screens: **Status**, **Run Status**, **Individual**, **Cumulative**, **Control**, and **Install**. Use these screens to install, view and edit controls, and to manage quality control results.

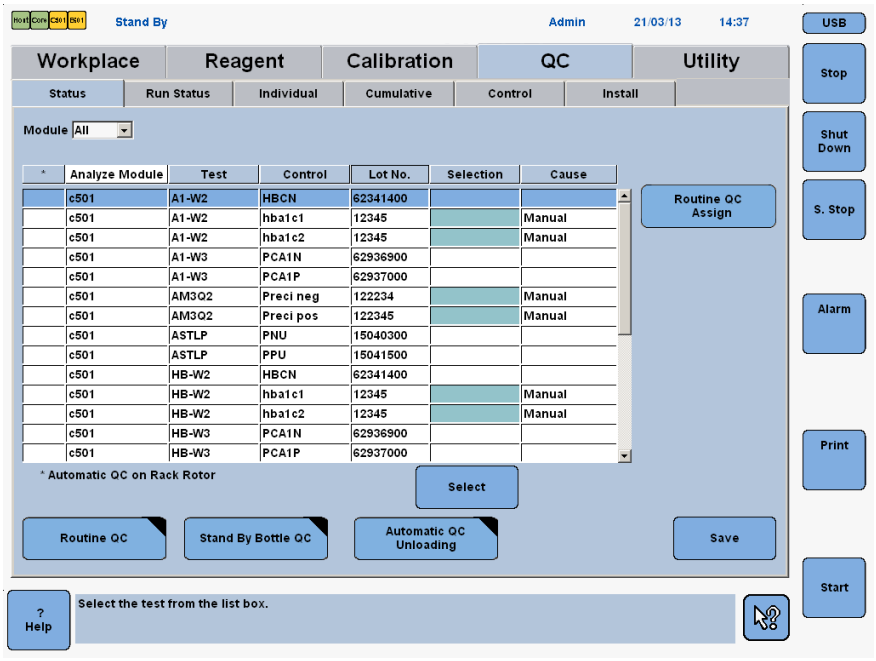


Figure B-15 QC menu

For more information, see:
QC Status screen on page B-202
QC Run Status screen on page B-207
QC Individual screen on page B-209
QC Cumulative screen on page B-217
QC Control screen on page B-218
QC Install screen on page B-220

Utility

The **Utility** menu consists of 7 screens: **System, Maintenance**, **Application**, **Calculated Test**, **Special Wash**, **Report Format**, and **Module Set**. These screens are used to enter system parameters, application parameters, maintenance settings and system settings.

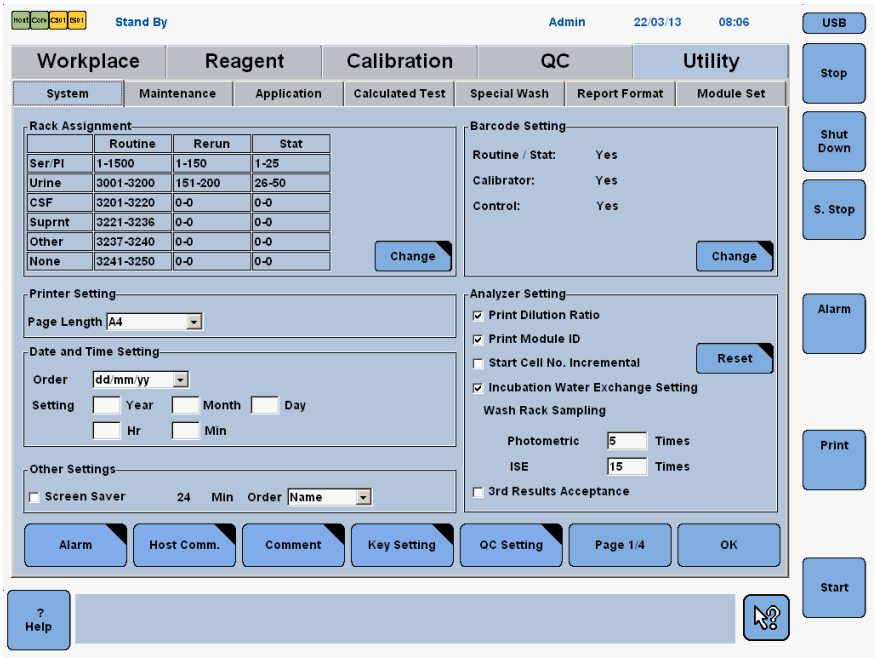


Figure B-16 Utility menu

For more information, see:
System configuration on page B-277
Performing maintenance items or pipes on page C-13
Application on page B-251
Calculated Tests (c 501) on page B-291
Special Wash on page B-297
Report Format on page B-306
Module Set on page B-287

Daily operation

This chapter provides a description of the everyday tasks which are required for running the **cobas** 6000 analyzer. Common procedures that are performed as part of the daily workflow are also described here.

In this chapter *Chapter* 8

Overview B-29
Starting the analyzer B-30
Starting inspection B-30
Start-up B-31
Automatic start-up B-32
Manual start-up B-33
Check system alarms B-34
System Overview screen B-35
Color scheme of the System Overview screen B-37
Work Flow Guide B-40
Preventive action B-40
Function of the Work Flow Guide elements B-41
Preroutine operation B-43
Daily Maintenance button B-43
Sample Data Clear button B-44
Reagent Preparing button B-44
c 501 – ISE unit B-45
c 501 – photometric unit B-49
e 601 B-50
Calibration and QC Select button B-51
Requesting calibration and QC and printing load lists B-52
Measuring calibrators and controls B-56
Validating calibration and QC results B-57
Parameter Download button B-58
Sample Tracking button B-60
Routine operation B-61
Processing routine samples B-62
Test selection B-62
Loading routine samples B-63
Starting the measurement B-64

Processing STAT samples B-65
Test selection B-65
Loading STAT samples B-66
Processing reruns B-67
Reruns with diluted samples B-68
Prediluted samples B-69
Checking results B-70
Sample tracking B-70
Printing sample information B-72
Sampling Stop B-73
Shutting down the analyzer B-74
Maintenance before shutdown B-74
Analyzer shutdown B-74
Checks after shutdown B-76

Overview

Pay attention to the safety precautions!

Before operating the instrument, observe the general safety information.

See *General safety information* on page A-3.

Daily operation encompasses the routine tasks that are required to prepare the analyzer, analyze samples, and maintain the analyzer. The layout of the **System Overview** screen gives the operator an intuitive guide for the tasks required for routine operation.

The following diagram gives an overview of daily operation.

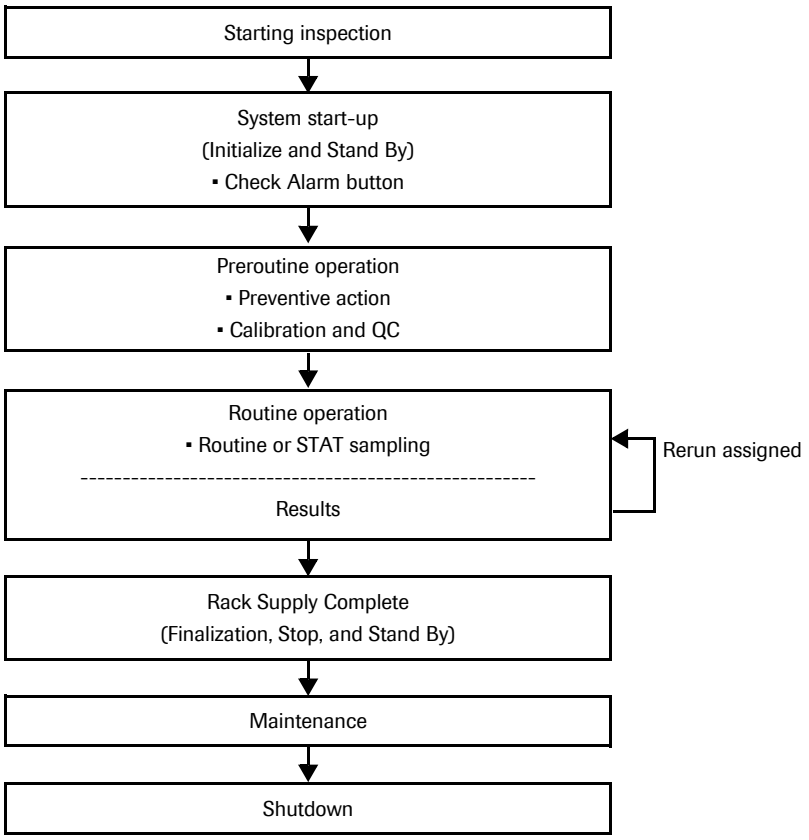


Figure B-17 Workflow diagram

Starting the analyzer

Before you can start routine operation, you must prepare the analyzer for operation.

For more information, see:
Work Flow Guide on page B-40
Preventive action on page B-40

Starting inspection

Before start-up, it is important that the following conditions of the analyzer are checked. Take the necessary action if a condition is not as listed below.

Control unit
- ☐ There is no floppy disk; CD or DVD in the corresponding drive.
- ☐ There is sufficient paper in the printer.

Core unit
- ☐ The water supply is switched on.
- ☐ Container for high concentrated waste is empty, clean and placed in the correct position.
- ☐ All connections and fittings of tubes and containers are connected properly and leak-proof.
- ☐ There are no racks on the rack loader, unloader, rack rotor, or conveyor line.

Analytic modules
- ☐ All surfaces are clean and clear of loose articles.
- ☐ No tubing is pinched or bent.
- ☐ Syringes are not leaking.
- ☐ Auxiliary reagents (cleaning solutions) required for start-up pipes are loaded.

***c** 501 module – ISE unit*
- ☐ All electrode cables and tubings are correctly connected. Tubing is not leaking.

***c** 501 module – photometric unit*
- ☐ All reagent cassettes are removed from the cassette disposal.
- ☐ Top cover of the **c** 501 module is closed and locked.

***e** 601 module*
- ☐ The amount of ProbeWash solution (near the reagent probe) is sufficient.
- ☐ The magazine door and drawer are closed.
- ☐ Syringes are not leaking.

If any problems arise, refer to the module-specific maintenance and troubleshooting chapters.

If the analyzer has been set for automatic start-up, it is important that the above checks are done as part of the maintenance at the end of the previous working session; otherwise, problems may occur.

Start-up

The analyzer can be started manually or automatically. The analyzer (**c** 501, **e** 601, and control unit) performs initialization and then enters standby mode (time approximately 12 min).

Automatically starting up the analyzer allows the analyzer to perform initialization before the beginning of a working session. When the operator arrives, the analyzer is ready for operation. To automatically start up the analyzer you have to do two things:

1. Configure the **Power Up pipe** function (set a wake-up time).
2. Put the analyzer in sleep mode at the end of the previous working session.

For more information, see:
Power Up Pipe function on page C-15
Analyzer shutdown on page B-74

Preparatory maintenance

Certain preparatory maintenance items are recommended to be executed after each analyzer start-up and before the start of analysis. To automate this preparatory maintenance use maintenance pipes in connection with the **Power Up pipe** or **Start Up pipe** functions.

For more information, see:
Maintenance pipes on page C-10
Daily maintenance on page C-24
Recommended maintenance pipes on page C-32

If you do not use maintenance pipes in connection with the **Power Up pipe** or **Start Up pipe** functions, you have to execute the maintenance items manually.

See *Performing maintenance items or pipes* on page C-13.

Visual checks

Even though you can automatically execute preparatory maintenance pipes using the **Power Up pipe** or **Start Up pipe** functions, some maintenance items require visual checks by the operator. Be sure to perform these checks prior to routine operation.

See *Visual checks at start-up* on page C-24.

Automatic start-up

The analyzer can be programmed to start up automatically.

If the analyzer was put in sleep mode at the end of the previous working session and a wake-up time was set, the analyzer starts up automatically at the set time. While the analyzer is performing initialization, the **Logon** screen is displayed.

For information, see:
Power Up Pipe function on page C-15
Analyzer shutdown on page B-74

► To automatically start up the analyzer

1 If the **Alarm** button on the right of the screen is flashing, check the **Alarm** screen for important system notifications.



See *To review the Alarm screen* on page B-34.

If the **Alarm** button is not flashing, go to step 2.



Figure B-18 **Logon** screen

2 Enter your **Operator ID** and **Password** to log on.

Passwords are case sensitive.

3 Choose **OK** to gain access to the software and begin operation. When initialization is completed, the analyzer goes into standby.

■

Manual start-up

If no automatic start-up has been set, use the following procedure to start up the analyzer.

If the logon mode is not activated (**Utility** > **System** (**Page 3/4**) > **Operator ID**), the software starts up displaying the **System Overview** screen.

► To manually start up the analyzer

1 Switch on the operation power switch, located on the left side of the rack sampler unit.

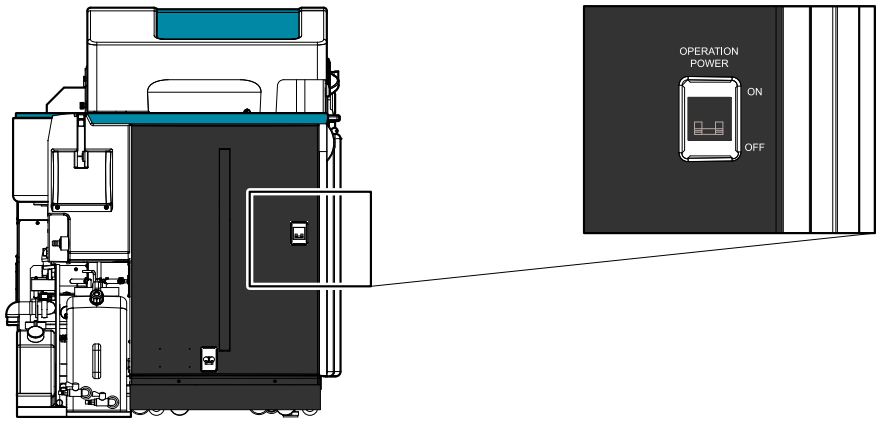


Figure B-19 Operation power switch

2 Switch on each power switch of the computer, printer, and monitor.

The analyzer starts the initialization routine (time for **c** 501, **e** 601, and control unit approximately 12 min).

While the analyzer is performing initialization the **Logon** screen is displayed.

3 Enter your **Operator ID** logon and **Password** to log on.

4 Choose **OK** to gain access to the software and begin operation. When initialization is completed, the analyzer goes into standby.

■

Check system alarms



If an alarm was issued, the **Alarm** global button flashes. In this case, it is necessary to open the **Alarm** screen to view the alarm. The **Alarm** screen identifies any system alarm conditions.

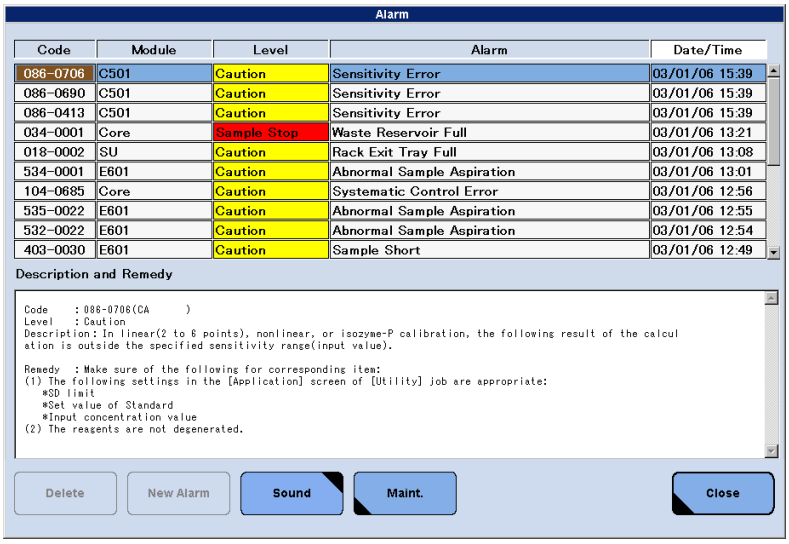


Figure B-20 **Alarm** screen

► To review the Alarm screen

1. Choose **Alarm** (global button) to display the **Alarm** screen.
2. Select each alarm to view the description and remedies (displayed in the lower half of the screen).
3. Correct any alarm conditions by following the remedies.

 If any problems arise, refer to the module specific troubleshooting chapter.
4. Choose **Close** to close the **Alarm** screen.

■

System Overview screen

The **System Overview** screen has a central role within the **cobas** 6000 software. The operator has an overview of the whole system at any given time and the modules can be prepared for daily routine operation via the **Work Flow Guide**.

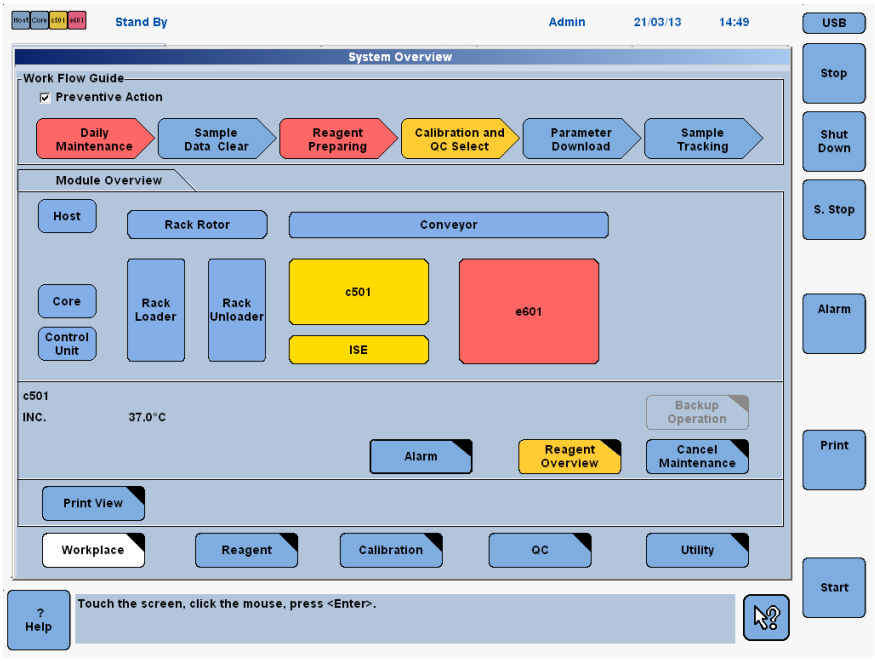
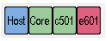


Figure B-21 System Overview screen



From any point in the software—**Workplace**, **Reagent**, **Calibration**, **QC**, or **Utility**—the **System Overview** screen can be accessed by choosing the icon in the top left corner of the screen or by pressing F12.

Work Flow Guide area

The **Work Flow Guide** area at the top of the **System Overview** screen guides you through the preroutine operation.

Module Overview area

The **Module Overview** area provides a view of the current status of the modules and components (for example, rack loader, unloader, **c** 501 module, and **e** 601 module) of the **cobas** 6000 system.

The lower section of the **Module Overview** area displays information relevant to the module or component currently selected such as incubator temperature (INC.).

*Temperature (**e** 601)* Choose this button to display the **Temperature** window. This window displays actual, target and control temperatures for the **e** 601 module currently selected.

Alarm This button displays the color corresponding to the highest priority alarm of the currently selected module or component. Use this button to display the global **Alarm** screen. The alarm(s) corresponds to the module or component currently selected.

Reagent Overview Choose this button to display an overview of the reagents loaded on the module currently selected.

See *Reagent Overview button* on page B-141.

*Backup operation (**c** 501)* In case of problems with the rack sampler unit, the backup operation mode allows to continue sample measurement on **c** 501 modules.

See *Backup operation* on page B-240.

Cancel Maintenance Use this button to stop all maintenance items running on the currently selected module after confirmation.

Some maintenance items performed on the analyzer cannot be stopped after start.

Print View Use this button to display the **Print View** window. This window is used to view reports in the print buffer, to print and also to write reports to a data storage medium.

Color scheme of the System Overview screen

The **System Overview** screen uses a color scheme to display the status of the analyzer.

The following table describes the meaning of the color scheme for each button/module on the **System Overview** screen.

Colors of the modules in the status line



Figure B-22 Status line

Red	Indicates an instrument alarm of **Stop**, **S.Stop** or **E.Stop** level or a reagent is empty and there is no second **cobas c** pack or **cobas e** pack on this particular module, or a mandatory reagent is not on board.
Yellow	Indicates an instrument alarm with a caution level or the number of remaining tests is less than the yellow alarm level.
Pink	Indicates reloading of reagents possible (reagent reloading function of **e** 601) 👁 See *Reagent reloading (e 601)* on page B-128.
Purple	Indicates the number of tests remaining for a diluent, test reagent or detergent volume is less than the purple alarm level (daily requirement)—only applicable when **Preventive Action** check box is checked.
Light blue	Indicates a status other than **Stand By** (e.g., **Operation** or **Maintenance**).
Light green	Indicates **Stand By** mode.
Dark green	Indicates an administrator has inactivated the module.
Black	Indicates the module is powered off.
X in a module	Indicates the module is masked.
\ in a module	Indicates the module is service masked.

👁 For information about instrument status, see *Instrument status* on page B-233.

Colors in the Work Flow Guide

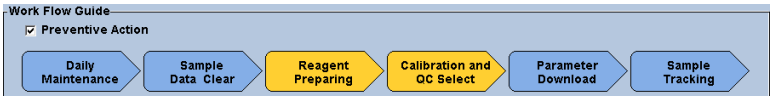


Figure B-23 Work Flow Guide area of the System Overview screen

Button in Work Flow Guide area	Color	Meaning
Daily Maintenance	Red	A maintenance item has expired.
	Yellow	A maintenance item is about to expire.
Sample Data Clear	Red	The database is full, 10 000 records. No additional samples can be processed until database (**Routine** view) is cleared.
	Yellow	The database is nearly full (more than 9400 records).
Reagent Preparing	Red	Reagent for at least one test or detergent required for the test is not on board (mandatory) or is empty.
	Yellow	The number of tests remaining for a reagent is less than the yellow alarm level.
	Purple	The number of tests remaining for a diluent, test reagent or detergent volume is less than the purple alarm level (daily requirement)—only applicable when **Preventive Action** check box is selected.
Calibration and QC Select	Yellow	One or more calibration or quality control is recommended. See *Calibration and QC Select button* on page B-51.
Parameter Download	Red	A **cobas c** pack or **cobas e** pack barcode, calibrator barcode, or QC barcode was read by the analyzer, which has not been installed before. New calibrator lots, QC lots and applications need to be installed before placing on the analyser.

Table B-4 Color scheme Work Flow Guide area

For more information about the **Work Flow Guide**, see *Work Flow Guide* on page B-40.

Colors in the Module Overview

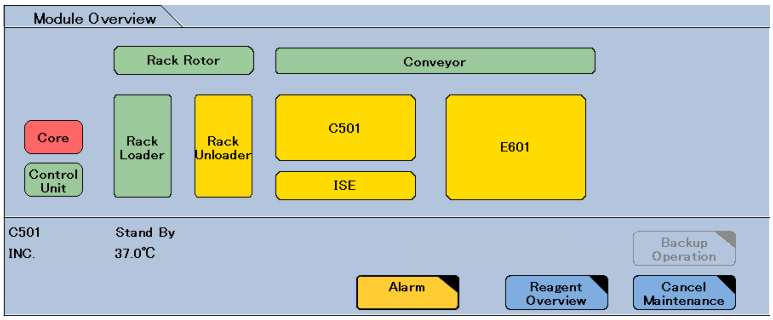


Figure B-24 Module Overview area of the System Overview screen

Button in Module Overview	Color	Meaning
Rack Rotor, Conveyor, Core, Control Unit, Rack Loader, Rack Unloader, C501, ISE, E601	Red	An instrument alarm of **Stop**, **S.Stop** or **E.Stop** level.
	Yellow	An instrument alarm with a caution level.
	Light blue	Indicates a status other than **Stand By** (e.g., Operation or Maintenance).
	Light green	Indicates **Stand By** mode.
Module	Red	Indicates an instrument alarm of **Stop**, **S.Stop** or **E.Stop** level or a reagent is empty and there is no second **cobas c** pack or **cobas e** pack on this particular module, or a mandatory reagent is not on board.
	Yellow	Indicates an instrument alarm with a caution level or the number of remaining tests is less than the yellow alarm level.
	Pink	Indicates reloading of reagents possible (reagent reloading function of **e** 601) 👁 See *Reagent reloading (e 601)* on page B-128.
	Purple	Indicates the number of tests remaining for a diluent, test reagent or detergent volume is less than the purple alarm level (daily requirement)—only applicable when **Preventive Action** check box is checked.
	Light blue	Indicates a status other than **Stand By** (e.g., **Operation** or **Maintenance**).
	Light green	Indicates **Stand By** mode.
	Dark green	Indicates an administrator has inactivated the module.
	Black	Indicates the module is powered off.
	X in a module	Indicates the module is masked.
	\ in a module	Indicates the module is service masked.
Reagent Overview	Red	A reagent is empty and there is no second reagent cassette or **cobas e** pack on this particular module, or a mandatory reagent is not on board.
	Yellow	The number of tests remaining for a reagent is less than the yellow alarm level.
	Purple	The number of tests remaining for a reagent is less than the purple alarm level.
Alarm	Red	Indicates an instrument alarm of **Stop**, **S.Stop** or **E.Stop** level
	Yellow	Indicates an instrument alarm with a caution level

Table B-5 Color scheme Module Overview area

Work Flow Guide

The **Work Flow Guide** area at the top of the **System Overview** screen guides you through the preroutine operation.

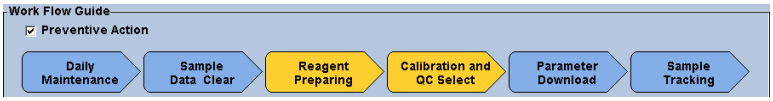


Figure B-25 Work Flow Guide

The **Work Flow Guide** area consists of 6 buttons: **Daily Maintenance**, **Sample Data Clear**, **Reagent Preparing**, **Calibration and QC Select**, **Parameter Download**, and **Sample Tracking**. The first 4 buttons are placed in the suggested sequence of preventive action. If a button remains blue, that action is not necessary.

The **Sample Tracking** button is used for locating samples on the analyzer and unloading selected racks from the system.

For more information about the different buttons, see:
Colors in the Work Flow Guide on page B-38
Preventive action on page B-40
Daily Maintenance button on page B-43
Sample Data Clear button on page B-44
Reagent Preparing button on page B-44
Calibration and QC Select button on page B-51
Parameter Download button on page B-58
Sample Tracking button on page B-60
Tracking samples on the analyzer on page B-98

Preventive action

Preventive action is a look ahead at what might be required during the daily routine. When activated, preventive action triggers the following items:

- Reagent purple alarm (diluent, test reagent or detergent volume is less than the daily requirement).
- Recommended calibration for tests with calibrations due within the **Remaining Time** set on the **Calibration Status** screen.

Yellow and red alarms have higher priority than the purple alarm.

At wake up or power on, the **Preventive Action** check box on the **System Overview** screen is automatically selected and therefore active.

It is recommended to deselect the **Preventive Action** check box after all recommended reagents are loaded and recommended calibrations have been performed.

Recommended calibrations are only performed if they were confirmed and accepted by the operator.

Function of the Work Flow Guide elements

Table below shows the links, configuration, and actions on the **Work Flow Guide**.

Button	Option	Link	Configuration	Action
Daily Maintenance		**Utility** > **Maintenance** screen	**Utility** > **System** (**Page 2/4**) > **Pipe Setting**	Perform maintenance issues
Sample Data Clear		**Sample Data Clear** window		
	Clear	**Workplace** > **Data Review** > **Delete All**	no configuration	Delete all sample records, move QC data to **QC View** database
	Backup and Clear	**Workplace** > **Data Review** > **Backup Data**	no configuration	Copy sample records to a special File Format
Reagent Preparing		**Reagent Preparing** window		
	Reagent Load List	**Print** (global button) > **Reagent Information** > **Reagent Load/Unload List** > **Print**	**Utility** > **System** (**Page 2/4**) > **Reagent Level** **Utility** > **Module Se**t > **Test Assignment** > **Module** button *Assigning a test to a module* on page B-288	Print **Reagent Load/Unload** list
	Open Channel for c 501	**Reagent** > **Setting** > **Open Channel** > **Open CH Selection**(**c** 501) window	no configuration	Reserve a channel for a **cobas c** pack MULTI
	Reagent Prime	**Reagent** > **Setting** > **Reagent Prime** *Reagent Prime* on page B-125	no configuration	Prime the ISE reagents

Table B-6 Options, Links, configuration, and actions of the Work Flow Guide (Sheet 1 of 2)

Button	Option	Link	Configuration	Action
Calibration and QC Select		**Calibration and QC Select** window		Indicates recommended calibrations and QCs
	Start Up	**Calibration** > **Status** > **Start Up**	**Calibration** > **Status** > **Start Up Setting** *Selecting tests for start-up calibrations* on page B-177	Request Start Up calibration
	Recommended		**Utility** > **Application** > **Calib.** *Auto calibration* on page B-265	Request recommended calibration
	Routine QC	**QC** > **Status** > **Routine QC Assign** *Routine QC Assign* on page B-203	**QC** > **Install** *QC Install screen* on page B-220	Request routine QC
	Stand By Bottle QC	**QC** > **Status** > **Stand By Bottle QC** > **Select** (all) *To perform controls for standby reagents* on page B-206	no configuration	Request stand by bottle QC
	Timeout		**Utility** > **Application** > **Range** > **Control Interval Time** *Control interval time* on page B-272	Request recommended timeout QC
	QC	**Print** (global button) > **QC** > **QC Load List** > **Print**	no configuration	Print **QC Load** list
	Calibration	**Print** (global button) > **Reagent Information** > **Reagent Load/Unload List** > **Print**	no configuration	Print **Calibration Load** list
Parameter Download		**To Do List** window		Indicates availability of new information on **cobas** link
	Application	**Utility** >**Application** > **Analyze** > **Download**	no configuration	Download application data *Downloading new application parameters* on page B-255
	Calibrator	**Calibration** > **Install** > **Download**	no configuration	Download calibrator data *Downloading or updating calibrator data* on page B-184
	Control	**QC** > **Install** > **Download**	no configuration	Download QC data *Downloading control data* on page B-221
SampleTracking		**Sample Tracking** window	no configuration	Check sample status View sample results Unload sample racks *Tracking samples on the analyzer* on page B-98

Table B-6 Options, Links, configuration, and actions of the Work Flow Guide (Sheet 2 of 2)

Preroutine operation

Preroutine operation involves the following tasks:

- Performing maintenance actions
- Clearing and backing up data, if necessary
- Download of parameters, if necessary
- Preparation of reagent
- Calibration
- Measurement of quality controls

The **Work Flow Guide** area at the top of the **System Overview** screen guides you through the preroutine operation.

Daily Maintenance button

Requirements: Define maintenance types

The **Daily Maintenance** button indicates when maintenance is about to expire. However this function is available only if maintenance intervals for maintenance items are defined.

For more information, see:
Color scheme Work Flow Guide area, Table B-4 on page B-38
Maintenance types—scheduling and tracking maintenance items on page C-9

Choosing **Daily Maintenance** on the **Work Flow Guide** area displays the **Maintenance** screen. Use the **Maintenance** screen to execute maintenance actions or maintenance pipe functions.

See *Performing maintenance items or pipes* on page C-13.

Define a power up pipe

For a proper use of the analyzer Roche Diagnostics recommends performing some maintenance items regularly. We recommend automating these maintenance items by means of maintenance pipes.

See *Recommended maintenance pipes* on page C-32.

Daily maintenance items may be programmed as a power up pipe and then performed automatically when powering on the analyzer or as a daily pipe if you do not shut down the analyzer daily.

To backup the data of your **cobas** 6000 system to **cobas** link we recommend including the maintenance item Smart. Com Essential information upload into the power up pipe or in the daily pipe.

For more information, see:
Power Up Pipe function on page C-15
Start Up pipe function on page C-16

Sample Data Clear button

Use the **Sample Data Clear** button to delete the contents of the database (**Workplace** > **Data Review** > **Routine View**).

For more information, see *Color scheme of the System Overview screen* on page B-37.

If **Sample Data Clear** is executed, all records of the samples are deleted and QC data is moved to the **QC View** data base. Less sample data in the database allows faster access to the data. Backing up on a periodic basis is recommended. If your system is connected to a Host, make sure that all data has been uploaded before performing the **Sample Data Clear**.

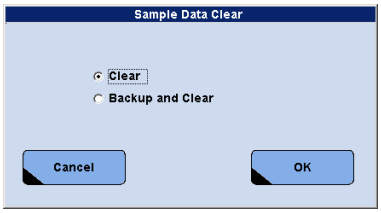


Figure B-26 Sample Data Clear window

For more information on saving data, see:
Archiving patient data on page B-91
QC data base management on page B-200

Operation of the analyzer may slow down

If the database for patient results or QC results is overloaded, the operation of the analyzer software may slow down. If the sample count in **Data Review** exceeds 10,000, the analyzer automatically goes into stop mode.

- It is strongly recommended to delete the contents of **Data Review** daily.
- Make sure that the results are transferred to the Host or saved on external storage media before deleting the contents of **Data Review**.

Reagent Preparing button

Requirements: Define reagent warning levels and mandatory tests

The **Reagent Preparing** button indicates insufficient amount of reagent. However, this function is available only if the volumes for the reagent level check and the mandatory tests were defined.

For information on the color scheme, see *Color scheme of the System Overview screen* on page B-37.

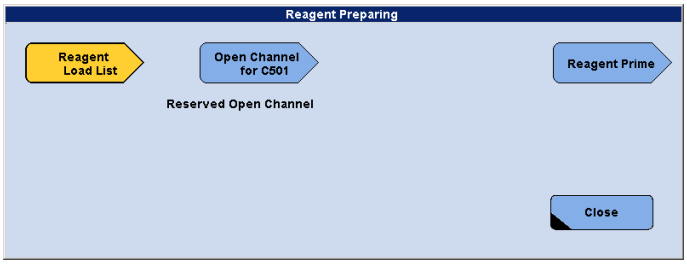


Figure B-27 Reagent Preparing window

Print Reagent Load List

The **Reagent Load List** displays the **cobas c** packs, **cobas e** packs, auxiliary reagents and other consumables that need to be replenished on the analyzer.

► To print a Reagent Load List/Unload List

1 Choose **Reagent Preparing** on the **System Overview** screen.

2 Choose **Reagent Load List** on the **Reagent Preparing** window.

A confirmation window appears.

3 Choose **Yes** to print the **Reagent Load List/Unload List**.

■

Now, remove and replace any required reagent, diluent, detergent or wash solution according to the **Reagent Load List/Unload List**.

Ensure that reagents have not exceeded their expiration dates. Check the expiration status on the **Reagent Overview** screen.

For more information, see:
Reagent Overview c 501 module on page B-141
Reagent Overview e 601 module on page B-147

c 501 – ISE unit

ISE IS, ISE Ref., and ISE Dil. are stored in reagent bottles in the ISE reagent compartment. A green indicator lamp (next to the reagent position) lights up if no reagent bottle is present or if the liquid level falls below the limit where the bottle needs to be replaced. In this case the ISE probe pipettes from the second bottle (standby bottle) of the reagent. If the standby bottle of ISE IS is used as changeover reagent, a changeover calibration is automatically recommended by the system.

When replacing an ISE reagent bottle, the remaining volume is reset. Before starting a measurement, reagent level is detected by using the ISE reagent probe to check the remaining volume of reagent so that the number of available tests can be controlled.

See *ISE reagent volume* on page B-106.

Hints for replacing ISE bottles

- Always use new bottles.
- Make sure bubbles are not formed in the ISE bottle. If bubbles formed, the liquid volume may not be detected correctly by the liquid level detection.
- After replacing an ISE reagent, recalibrate the ISE unit before you resume routine operation.

Evaporation of internal standard

Downward drift in controls and patient sample results can occur due to increased evaporation of the internal standard.

Evaporation of the internal standard can occur due to an unfavorable combination of low humidity, high altitude and air movement in the laboratory depending on the use of air conditioning or fans. Another contributing factor is the internal standard bottle filling level, since it has a direct impact on the concentration of the internal standard.

In case of proven or potential internal standard evaporation the use of a bottle insert for the internal standard is recommended.

For ordering the bottle inserts and information on the correct usage of the bottle inserts, please contact your Roche service representative.

► To replace ISE IS or ISE Dil.

Replacement during operation is allowed only in the position where the green LED is lit.

Replacement of ISE IS and ISE Dil. can be done with the top cover closed.

1 Insert the bottle insert in the new internal standard bottle, if necessary.

2 Remove the empty bottle from the position where the green indicator lamp lights up.

CAUTION! False result due to incorrect loading position. Take care to place the bottles in the correct positions as labeled.

3 Place a new bottle into the reagent position.

Reagent registration is performed automatically when a new bottle is placed.

■

► To replace ISE reference solution (ISE Ref.)

1 Put the module in standby.

2 Unlock and open the top cover of the module.

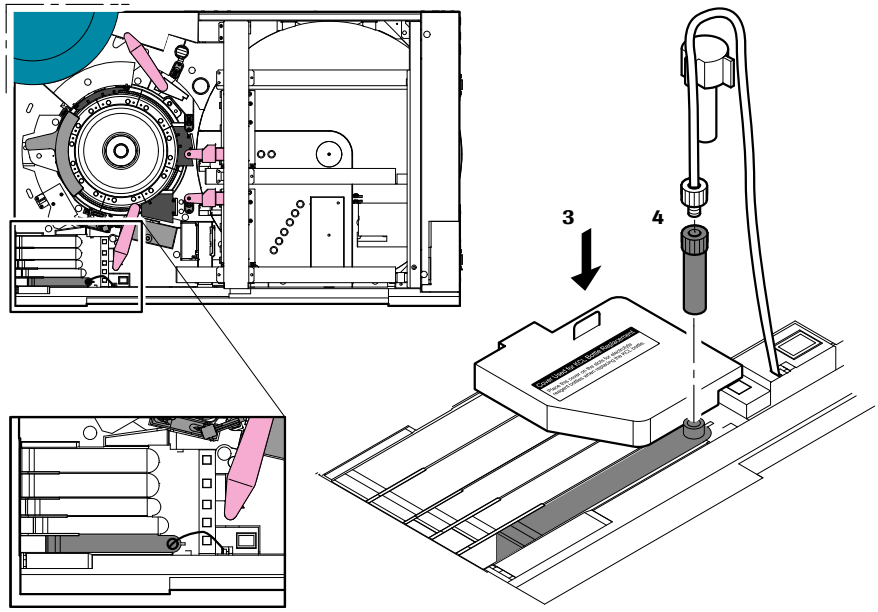


Figure B-28 Cleaning the ISE Ref. aspiration filter

CAUTION! Liquid from the tip of the tube may drop into another ISE reagent and may lead to false results. Place the dedicated cover over the ISE reagent bottles.

3 Place the dedicated cover over the ISE reagent bottles.

4 Remove the tubing from the ISE Ref. bottle and clean the ISE Ref. aspiration filter.

See *Cleaning the ISE Ref. (KCl) aspiration filter* on page C-84.

5 Replace the ISE Ref. bottle, and place the tubing into the new bottle. Make sure that the end of the tube touches the bottom of the bottle. Otherwise, reagent may not be pipetted properly.

The indicator lamp of the ISE Ref. bottle turns off.

6 Remove the dedicated cover from the ISE reagent bottles.

7 Close the top cover of the module and lock it.

Reagent registration is performed automatically when a new bottle is placed.

■

After replacing the ISE Ref. bottle, it is necessary to perform a **Reagent Prime**.

► To perform a Reagent Prime

1 From the **System Overview** screen, choose **Reagent Preparing**.

2 Choose **Reagent Prime** on the **Reagent Preparing** window.

3 Select a module. Selected modules are highlighted.

4 Choose **Ref** in the **ISE** area.

5 Choose **Execute**.

The prime is complete when the analyzer returns to stand by.

■

After the **Reagent Prime**, recalibrate the ISE unit before you resume routine operation.

👁 For details on how to recalibrate the ISE unit, see *Calibration and QC Select button* on page B-51.

c 501 – photometric unit

Replace all required **cobas c** packs and auxiliary reagents as indicated by the **Reagent Load List**. Ensure that reagents have not exceeded their expiration date.

*Replacing **cobas c** packs*

The **c** 501 module automatically unloads empty **cobas c** packs to the cassette disposal, which is located behind the left front door of the **c** 501 module. It is also possible to unload **cobas c** packs manually from the **Reagent** > **Setting** screen (only possible in standby).

For details see *Unloading reagent cassettes* on page B-127.

To load a new **cobas c** pack, follow the procedure below:

⚠ CAUTION

Injury due to contact with cassette loading mechanism

The instrument may recognize your hands or fingers as a **cobas c** pack if you insert your hands or fingers into the cassette loading port. An unloaded **cobas c** pack may hit your hands or fingers when the instrument is unloading **cobas c** packs.

- The **c** 501 module cover must be closed and locked when loading **cobas c** packs.
- Leave the cassette table closed, except when registering **cobas c** packs or when manually unloading **cobas c** packs from the **Reagent** > **Setting** screen.
- Do not insert anything other than **cobas c** packs into the cassette loading port.

► To load a cobas c pack

1. Fold the cassette table at the front of the **c** 501 module downward to get access to the cassette loading port.

 To locate the cassette loading port, see *Cassette loading port* on page A-75.

2. Place the **cobas c** pack right in front of the loading port with its **barcode label facing to the right**.
3. Slide the **cobas c** pack all the way into the loading port until you sense a resistance.

 From this point on the analyzer handles the **cobas c** pack without any further intervention of the operator: The **cobas c** pack is pulled in to the preparation station where the module automatically performs the reagent registration.

■

If a **cobas c** pack barcode is facing the wrong direction or the barcode is unreadable, a label reading error occurs and the **cobas c** pack is not registered. In this case the **cobas c** pack is rejected and will not be loaded but pushed out of the loading port.

Replacing auxiliary reagents

For instructions how to replace auxiliary reagents, see:
To replace a cell detergent bottle on page B-131
To replace Sample Cleaner 1 and 2 or EcoTergent on page B-131

e 601

Replace all required **cobas e** packs, auxiliary reagents and consumables on the respective modules as indicated by the **Reagent Load List**.

*Replacing **cobas e** packs*

To load a new **cobas e** pack, follow the procedure below:

⚠ CAUTION

Incorrect results due to incorrect reagent temperature

cobas e packs taken directly from the refrigerator may result in incorrect results.

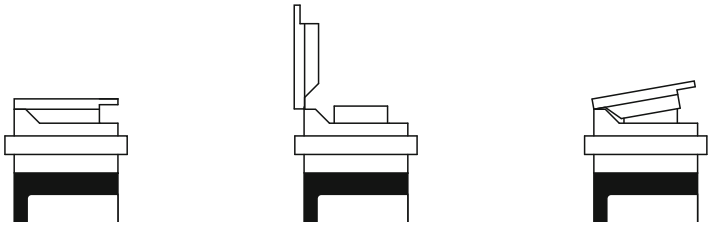
- Only insert **cobas e** packs of the correct temperature of 20 ±3 °C (68 ±5.4 °F)

► To load cobas e packs

CAUTION! Risk of personal injury and damage to the analyzer. Do not open the reagent disk cover while the module is in operation.

1. Make sure, that the system is in standby.
2. Lift off the lid of the reagent disk.

 👁 See *Reagent disk* on page A-98.
3. Open the caps of each **cobas e** pack manually and set the caps gently to the so called *soft-close* position: The caps are almost closed, but not tight closed.



A Cap: Closed **B** Cap: Open **C** Cap: Soft-close position

Figure B-29 Caps of **cobas e** pack: Soft-close position

4. Check that there are no microbeads deposited on the inside of the transparent reagent cap. If yes, discard the e pack.
5. Check that there is no foam or bubbles in any of the reagent bottles and no reagent film formed in the neck of the reagent bottles.
6. Place the required **cobas e** packs in the reagent disk. Ensure that the **cobas e** packs are placed in the reagent disk in the correct orientation.
7. Close the lid of the reagent disk. A reagent scan is started and the **Reagent Overview** window (**System Overview** > **Reagent Overview**), the **Reagent** > **Status** screen, and the **Reagent > Setting** screen are updated.

■

Replacing auxiliary reagents

👁 For instructions how to replace auxiliary reagents, see:
Replacing auxiliary reagents (e 601) on page B-132
Replacing consumables and emptying solid waste (e 601) on page B-139

Calibration and QC Select button

It is necessary to calibrate all applications and measure quality control (QC) samples regularly to verify the stability of reagents and the entire system. Make sure calibration has been completed successfully and all QC results are OK before you start routine operation.

The intervals of calibration and QC vary with each application and therefore each application has its individual configuration. According to this configuration, the system automatically recommends calibrations and QC measurements for all registered applications.

For details about calibration and QC intervals refer to the instructions for use of the corresponding test.

Each time the system recommends a calibration it is indicated by the **Calibration and QC Select** button turning yellow.

The following sections explain how a recommended calibration is executed. The instructions are given assuming that all configurations for calibration and QC are already set.

For general information on calibration, see:
Calibration concept on page B-155
Causes for automatic calibration recommendations on page B-156
Description of application parameters – Calib. tab on page B-263
To select tests for start-up calibration on page B-177

The entire calibration and QC process comprises the following parts:

1. Requesting calibration and QC and printing load lists
2. Measuring calibrators and controls
3. Validating calibration and QC results

The following explains each of these parts. However, some details depend on your laboratory's decision on a specific calibration workflow (for example, time-triggered calibration or QC-triggered calibration).

Requesting calibration and QC and printing load lists

The **Calibration and QC Select** button on the **System Overview** screen turns yellow when a calibration or quality control is recommended by the system.

Choose the **Calibration and QC Select** button to display the **Calibration and QC Select** window.

Use the **Calibration and QC Select** window to perform following actions:

- Accept the recommended calibrations or quality controls.
- Print a **Calibration** or **QC Load List**.

Notes on recommended calibrations and QC measurements

Calibration and QC measurements are recommended by the system only for applications which have their corresponding **cobas e** packs and **cobas c** packs loaded.

In case there are **cobas e** packs or **cobas c** packs on board with less than ten tests remaining, a confirmation window opens and it is possible to cancel the calibration or QC measurements request for this reagent.

Use the following procedure to request the recommended calibrations and controls. If you need to select additional calibrations manually, select these from the **Calibration** > **Status** screen.

See *Requesting and cancelling calibrations manually* on page B-167.

Requesting calibration and QC

To request calibration and QC, follow the procedure below:

► To request calibration and QC

1 Choose **Calibration and QC Select** in the **Work Flow Guide** area.

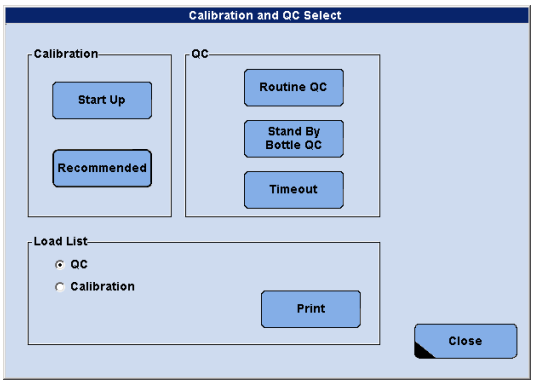


Figure B-30 Calibration and QC Select window

2 Choose the buttons that are yellow in both the **Calibration** area and the **QC** area to select the suggested calibrations and controls for measurement.

In case there are reagents with less than 10 tests on board, a confirmation window opens and it is possible to cancel the calibration or QC request for these reagents.

3 Select the list you want to print from the **Load List** area:

- **QC** comprises all requested QCs including QC after calibration.
- **Calibration** comprises all requested calibrations.

4 Choose **Print** to print the selected load list.

The **QC Load List** and the **Calibration Load List** respectively displays all controls and calibrators that are needed to perform the requested measurements.

If you need to run QC for stand by cassettes, do one of the following:

- Choose **Stand By Bottle QC** to request a QC for all stand by reagents.
- Choose **QC** > **Status** > **Stand By Bottle QC**, select individual tests from the list, and choose **OK**.

See *Requesting QC measurements* on page B-205.

5 Load the calibrators and controls on the analyzer as directed by the **Calibration Load List** and the **QC Load List**.

See *To load required calibrators and controls* on page B-55.

■

```
                                Calibration Load List              07/10/08   09:24

  NAME          LOT           R.NO.           EVENT     VOLUME
  H2O           99999900                     ------   --------
  CFAS          17715200                     ------   --------
  ISELOW        69906400      S0002-1        ------   --------
  ISEHIGH       69631400      S0002-2        ------   --------
  ISECOMP       18191800      S0002-3        ------   --------
  TSH-L1        182423                            2      196.0
  TSH-L2        182423                            2      196.0
```

Figure B-31 Calibration Load List report

```
                        QC Load List                                      27/11/08       16:59

----------------------------      System Specific Rack      -----------------------------
AUTOMATIC QC RACK RANGE       0000 -  0000

NAME          LOT               EVENT     VOLUME    R.NO.
PPU           17628700           ----   --------    C0001-2
PNU           17683000           ----   --------    C0001-1

----------------------------        QC After Calib.         -----------------------------
NAME          LOT               EVENT     VOLUME    R.NO.
PC U2         15041800              2       22.0
PC U1         18067700              2       22.0
PC CARD1      18269000              4       60.0    C0005-1
PC CARD2      18269100              4       60.0    C0005-2

----------------------------      Module Specific Rack      -----------------------------
MODULE E1     RACK RANGE          5- 10
NAME          LOT               EVENT     VOLUME    R.NO.
PC U2         15041800              2       22.0
PC U1         18067700              2       22.0
PC CARD1      18269000              4       60.0
PC CARD2      18269100              4       60.0
```

Figure B-32 QC Load List report



Hints about the Load Lists

- **Volume** is given only for **e** 601 determinations.
- If a rack number is displayed (**R. No.**), then a position assignment is stored in the software.
- Do not place barcoded calibrator and control vials on racks with position assignment.
- One **Event** for calibrator is pipetting this calibrator in duplicate for one measurement cell and one **cobas e** pack.
- One **Event** for quality controls is one determination for one parameter out of this quality control vial.

Loading calibrators and controls

To load calibrator and controls, follow the procedure below:

⚠ CAUTION

Incorrect results due to expired calibrators or controls

Data obtained using expired calibrators or controls are not reliable.

- Do not use calibrators or controls that have expired.

⚠ CAUTION

Incorrect results due to concentrated ISE calibrators

The concentration of the ions increases due to evaporation, this may result in an incorrect calibration, and thus incorrect results.

- For ISE calibrations set fresh calibrators just before the calibration is performed.
- Do not aliquot or store opened bottles of ISE calibrators low and high.

⚠ CAUTION

Incorrect results due to calibration or QC failure

If manually assigned vials and barcoded vials are on the same rack, the requested calibrations and controls are not measured and the requests are deleted.

- If a calibrator or QC vial (or another sample container) needs to be manually assigned (for example, due to an unreadable barcode) do not place any vials or other sample containers with barcodes on the same rack.
- Do not mix barcoded and non-barcoded vials in one rack.
- Do not use micro cups for calibrators and controls.

► To load required calibrators and controls

CAUTION! QC failure! In non-barcode mode, the system cannot calculate the remaining volume in the control vial (**e** 601). Ensure that sufficient control material is available.

1 Using the load list as a guide, prepare all required calibrator and control materials according to the manufacturer's instructions.

2 Check that no bubbles or foam are visible on the liquid surface.

CAUTION! Injury due to contact with rack loader mechanism. Only load samples onto the rack loader when the green light on the rack loader is on.

3 Load calibrators and controls onto the racks (calibrators onto black racks, controls onto white racks) and place the racks on the loader.

Two or more calibrator racks are to be measured as one group, so do not put other racks between them. When you carry out QC after calibration, QC racks have to follow calibrator racks directly. Do not set other racks with the calibrator and QC racks.

■

For more information, see:
To load calibrator vials on page B-180
To assign calibrator positions on page B-179
Sample racks on page A-59

Measuring calibrators and controls

Once calibrations and QCs are requested and the calibrators and controls placed on the loader, the measurements can be started.

► To measure calibrators and controls

1 Choose **Start** (global button).

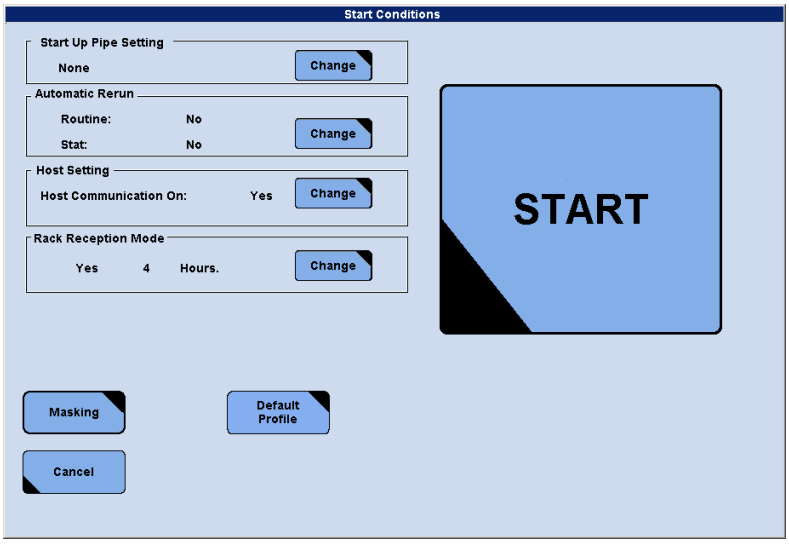


Figure B-33 Start Conditions screen

2 Choose **Start** on the **Start Conditions** screen. The **Start Conditions** screen closes and the calibration and control run begins.

If automatic printout is selected on **Utility** > **System** (**Page 4/4**) > **Auto. Print**, the **Calibration Monitor** and **Control Result Monitor** report is automatically printed when the measurements are completed; calibration and QC results can also be viewed choosing **Print** (global button) > **View**.

■

Validating calibration and QC results

It is important to verify that calibrations and QC results are valid before measuring routine samples. Validation can be performed either at the Host or on the **cobas** 6000 system. For routine operation it is sufficient to validate calibrations and QC by means of the **System Overview** screen:

A failed or newly recommended calibration is indicated on the **System Overview** screen by the **Calibration and QC Select** button turning yellow.

Information on the status of the calibrators that are currently processing can be viewed on the **Workplace** > **Calib. Review** screen.

See *Calib. Review screen* on page B-96.

Detailed information on calibration results can be viewed on the **Calibration** > **Status** screen.

See *Calibration Status screen* on page B-166.

Detailed information on quality control results can be viewed on **QC** > **Individual** screen.

See *QC Individual screen* on page B-209.

If the automatic printout of calibration or QC results is configured (on **Utility** > **System** (Page 4/4) > **Automatic Printout**), it is also possible to use these printouts for validation.

If calibration or QC failed…

If a calibration fails or a QC result falls out of the expected range, check for data alarms on the **Workplace** > **Calib. Review** screen or on the printouts.

Data alarms are issued when measurement values or results are in any way unusual or unexpected. Data alarms appear on screen and on reports as short strings (up to six characters) also referred to as data flags. Look up the meaning of each data flag and possible remedies in the troubleshooting part of the Operator´s Manual.

See *Data alarms* on page D-3.

After taking the necessary measures, repeat the calibration or QC before you begin routine analysis.

If a realtime QC rule is violated, the system issues a realtime QC alarm. Ensure you check the results of the QC to see if you accept the values.

Quality control results

The results of QC measurements are saved in the database and displayed on the **Data Review** screen as well as on the **QC** > **Run Status** screen and **QC** > **Individual** screen. It is important to regularly accumulate these results for long term quality control data storage (**QC** > **Cumulative**).

See *Accumulate Data window* on page E-330.

Parameter Download button

The **Parameter Download** button turns red if a **cobas c** pack or **cobas e** pack, calibrator (**c** 501), or QC (**c** 501) was loaded onto the analyzer, which has not been installed before. New information for applications, controls, and calibrators must be downloaded from **cobas** link.

Choose **Parameter Download** in the **System Overview** screen to open the **To Do List** window.

Use **Download** button to display the appropriate screen. Depending on the tab that was selected on the **To Do List** window, one of the following screens is displayed:

- **Utility** > **Application**
- **Calibration** > **Install**
- **QC** > **Install**.

On each of these screens, you can initiate the download of the missing item from **cobas** link by choosing the **Download** button.

For an overview of downloading parameters from **cobas** link, see *Installing an application* on page B-252.

***cobas c** packs* The system-ID is displayed in the **Reagent Code** column. The system-ID is also displayed in the **Code** column in the **Reagent** > **Setting** screen.

*Calibrators and controls (**c** 501)* The first six digits of the lot number followed by 00 are displayed in the **Lot No.** column.

***cobas e** packs* The ACN is displayed in the **Reagent Code** column.

*Calibrators and controls (**e** 601)* An internal software number is displayed in the **Lot No** column. The internal software number is not the lot number.

► To download new information

1 Choose **Parameter Download** in the **Work Flow guide** area

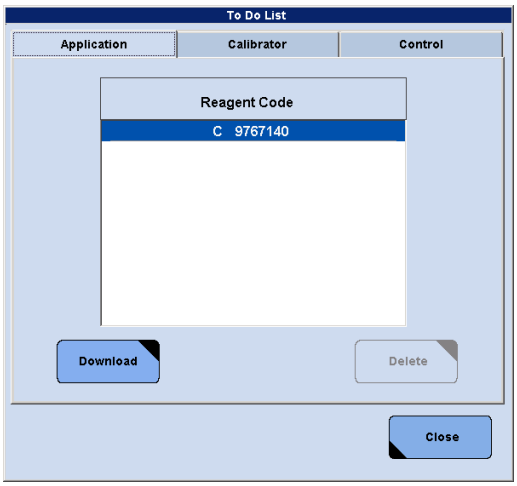


Figure B-34 To Do List window

2 Choose the tab of the corresponding items you want to download.

3 Select an item from the list and choose **Download**.

The corresponding screen will be opened, for example, the **Utility** > **Application** screen for application parameters.

4 Choose the **Download** button to open the **Download** window.

The following steps are described in the corresponding chapters:
Downloading new application parameters on page B-255
Downloading or updating calibrator data on page B-184
Downloading control data on page B-221

■

Sample Tracking button

The **Sample Tracking** window allows the operator to search for any sample on the analyzer from the moment of registration (the sample has passed the barcode reader) to the moment when the sample reaches the rack unloader (Tray 1).

The **Sample Tracking** window also allows the operator to search for samples and subsequently unload the rack containing the sample(s) of interest.

Notes on the Sample Tracking window

Only STAT and routine samples can be searched for in the **Sample Tracking** window.

The location of a sample is indicated by the **Sample Tracking** window only when the sample tray has not been removed from the unloader and no new run has been started yet.

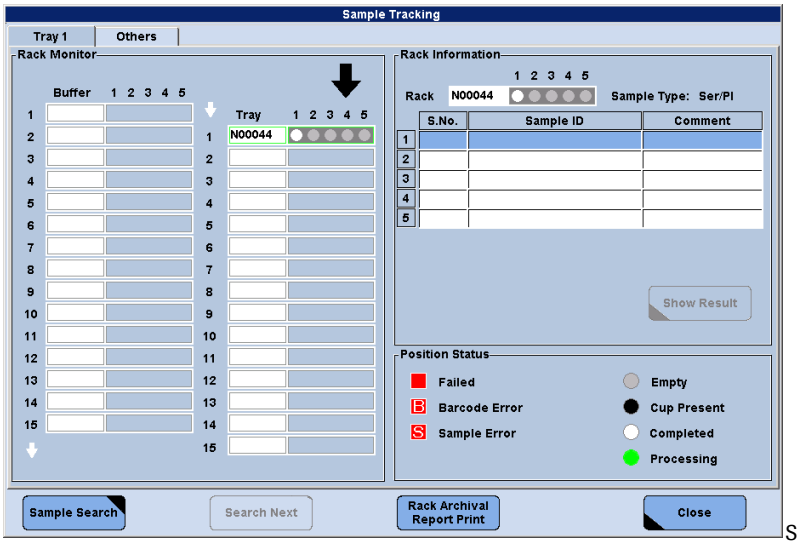


Figure B-35 Sample Tracking window

For more information, see:
Sample tracking on page B-70
Tracking samples on the analyzer on page B-98

Routine operation

Before continuing with routine operation, clear the **Preventive Action** check box on the **System Overview** screen. Otherwise, the system will issue purple and other irrelevant alarms in the course of routine operation.

Routine operation involves the following items:

1. Processing routine samples
2. Processing STAT samples
3. Processing reruns
4. Checking results
5. Sampling Stop

The way in which routine operation works varies depending on the following system settings and sample properties:

- Whether routine or STAT samples are being analyzed
- Whether the analyzer operates in barcode mode or not (set in the **Barcode Setting** area under **Utility** > **System**)
- Whether the analyzer operates in connection with a Host computer

⚠ CAUTION

Incorrect results when sample tubes are not aligned vertically

Incorrect placement of sample tubes in racks may cause incorrect sample pipetting, which may lead to false low results, especially when testing immunoassays.

- Always use the Roche Diagnostics cup adapter for sample tubes with an outer diameter of 13 mm or less.

See *Correct placement of sample tubes on a rack* on page A-62.

- Only use sample tubes specified for the use with the **cobas** 6000 analyzer series.

See *Sample cups and tubes* on page A-116.

Restrictions for the use of micro cups

When the end of sample probe touches the inner wall of a micro cup this may result in improper sample aspiration.

- Do not use micro cups on **e** 601 modules.
- Do not use micro cups for calibrators and controls.

Sample preparation

When preparing samples, always ensure that the preanalytical requirements are fulfilled according to good laboratory practice and tube manufacturer recommendations.

Processing routine samples

In this section, we describe the workflow for an analyzer that operates in connection with a Host and is set to process routine samples in barcode mode. Processing samples always includes the following three steps:

1. Test selection
2. Loading samples
3. Starting the measurement

For more information on ordering samples, see Chapter 9 *Orders and results.*

Test selection

Test selections for routine samples are downloaded from the Host. However, these test selections can manually be changed—regardless of the mode (**Stand By**, **Stop**, **Operation**, or **Sample Stop**) the analyzer is in.

For information on manual test selections, see *Requesting a test manually* on page B-83.

Loading routine samples

Once test selections have been made on your Host system or on the analyzer, load the samples onto the rack loader observing the notes below. If needed, print a requisition list from **Print** (global button) > **Work Place** > **Requisition List**.

For more information, see *Requisition List* on page E-88.

► To load patient samples

1 Prepare sample racks with the correct color and rack numbers according to sample types (such as Ser/Pl, Urine, CSF…).

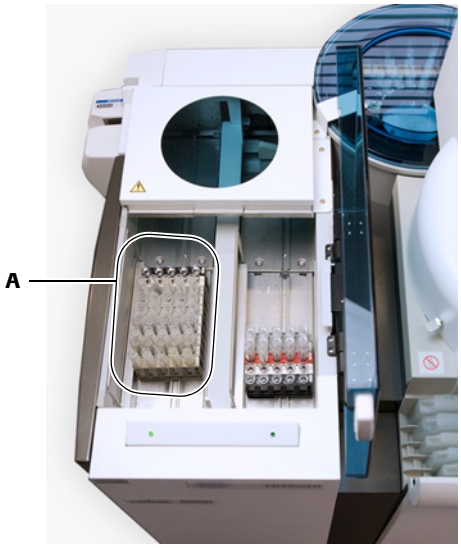
- For all routine samples use gray racks.
- To verify the correct rack numbers for each sample type refer to the **Rack Assignment** area on the **Utility** > **System** screen.

No test performed on rack

If you place samples in a wrong rack, e.g. urine samples in a Ser/Pl rack, a yellow alarm **No test performed on rack** occurs.

2 Place the samples in the prepared sample racks. Ensure the sample barcodes are facing the open slot in the rack so the barcode reader can scan them.

For more information, see *Correct placement of sample tubes on a rack* on page A-62.



A Rack loader

Figure B-36 Loading patient samples

CAUTION! Injury due to contact with rack loader mechanism. Only load samples onto the rack loader when the green light on the rack loader is on.

3 Place the routine sample racks onto a rack tray in the correct orientation: The barcode labels of the sample racks have to be on the right side when placing the tray into the rack loader. The rack loader is on the left side.

■

Starting the measurement

Before starting a run, ensure that all test selections have been made and all necessary samples, calibrators, and controls have been loaded.

► To start processing

1 Choose **Start** (global button).

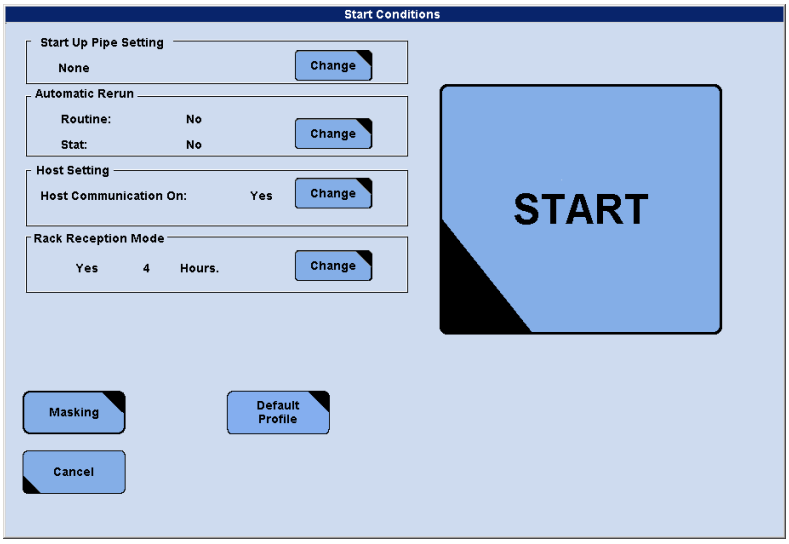


Figure B-37 Start Conditions screen

2 Verify the settings on the **Start Conditions** screen.

For more information on setting the start conditions, see:
Start Up pipe function on page C-16
To activate the automatic rerun function on page B-67
Rack Delivery button on page B-284

3 Choose **Start** (on the **Start Conditions** screen). The analyzer performs preparation routine and then begins to process the samples.

■

Processing additional samples

Additional samples can be loaded onto the analyzer at any time. There are two priority levels: STAT (emergency) and routine, where the first takes priority over the second. In either case, test selections for additional samples are downloaded from the Host in realtime.

For information on manual test selections, see *Requesting a test manually* on page B-83.

► To process additional samples

1 Load the additional samples either from the STAT port or on the rack loader (racks placed on a rack tray).

- If the analyzer is in operation, samples are processed without any further action.
- If the analyzer is not already in operation, go to step 2.

2 Choose **Start** (global button).

3 Choose **Start** on the **Start Conditions** screen to initiate the run.

Samples loaded from the STAT port are processed before those on the rack loader.

■

For unloading specific racks, see *To unload specific racks* on page B-100.

Processing STAT samples

In this section, we describe the workflow for an analyzer that operates in connection with a Host and is set to process STAT samples in barcode mode.

Reserve rack rotor positions for STAT samples

To ensure that a STAT sample can be processed immediately, reserve positions on the rack rotor for STAT samples on the **Rack Delivery** window (**Utility** > **System** (Page 3/4) > **Rack Delivery**).

Otherwise all positions might be used by routine samples.

For more information, see *Rack Delivery button* on page B-284.

Test selection

Test selection for STAT samples is the same as for routine samples. That is, test selections for samples are downloaded from the Host in realtime but can still be changed from the analyzer's control unit.

For information on changing test selections, see *Requesting a test manually* on page B-83.

Loading STAT samples

Once test selections have been made on your Host system or on the analyzer, load the STAT samples onto the analyzer using the STAT port observing the notes below.

NOTICE

Instrument damage when a rack is inserted wrongly

The instrument normally issues an alarm if a rack was inserted wrongly in the STAT port. However, under certain circumstances a wrong rack direction cannot be detected, which may possibly lead to instrument damage.

- Ensure the correct orientation of the rack when loading it into the STAT port.

► To load STAT samples

1 Prepare red STAT racks with the correct rack numbers according to sample types (such as Ser/Pl, Urine, CSF…).

To verify the correct rack numbers for each sample type refer to the **Rack Assignment** area on the **Utility** > **System** screen.

If a barcode read error has occurred and the rack position has been manually assigned, be sure not to place another barcoded sample in that position.

2 Set the samples in the prepared sample racks. Ensure the sample barcodes are facing the open slot in the rack so the barcode reader can scan them.

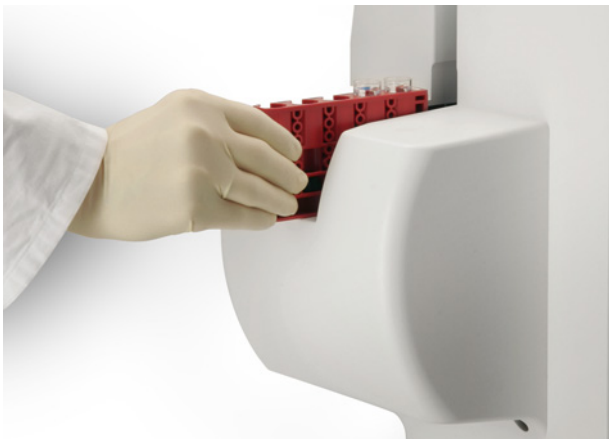


Figure B-38 Loading STAT samples

3 Place the STAT rack in the STAT port carefully observing its correct orientation:

The open slots in the racks must point to the rear of the rack sampler unit. The side of the STAT rack with the barcode label must point to the analyzer.

■

For unloading specific racks, see *To unload specific racks* on page B-100.

Processing reruns

Rerun samples can be processed in two ways, as automatic reruns or as manual reruns.

For information on manual test selections, see *Requesting a test manually* on page B-83.

Automatic reruns

Automatic reruns are performed depending on whether the **Automatic Rerun** check box on **Utility** > **Application** > **Range** is selected or not. If it is, the test is automatically requested for rerun and remeasured each time a result is flagged with a data alarm. Selection of the **Automatic Rerun** check box is an application-specific setting; that is, it has to be set for each individual application.

See *Automatic rerun* on page B-271.

In addition to the application-specific setting, there is a system-wide setting for the automatic rerun function. It is displayed in the **Automatic Rerun** area on the **Start Conditions** window:

See Figure B-37 on page B-64.

- If **Automatic Rerun** is set to **YES**, the application-specific settings are applied; the automatic rerun function is activated.
- If **Automatic Rerun** is set to **NO**, reruns are to be processed manually (regardless of application-specific settings).

When processing reruns automatically, sample racks are kept in the rack rotor until all samples' results are available.

► To activate the automatic rerun function

1 Verify the settings of the **Automatic Rerun** check box on **Utility** > **Application** > **Range** (application-specific).

2 Choose **Start** (global button).

3 Choose **Change** in the **Automatic Rerun** area.

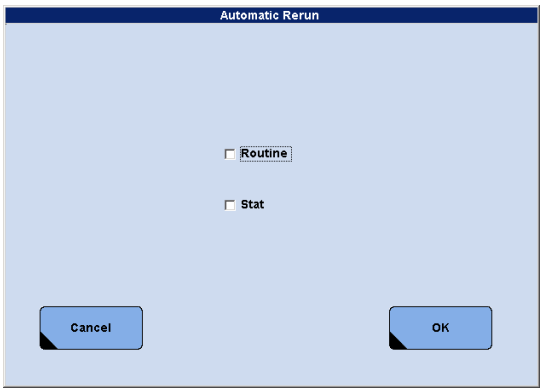


Figure B-39 Automatic Rerun window

4 Choose the **Routine** check box, **Stat** check box, or both to process reruns without operator intervention. **Routine** and **STAT** reruns are selected separately.

5 Choose **OK** to save the rerun setting.

■

Manual reruns

If **Automatic Rerun** is set to **NO** in the **Start Conditions** window, all reruns are to be processed manually (regardless of application-specific settings). This is of advantage when you aim for an optimized throughput because no racks will have prolonged rotor times while waiting for the last test results before they are transferred to the unloader.

To manually rerun samples *in barcode off mode* use pink sample racks for the sample containers. To rerun samples *in barcode mode* use gray sample racks for the sample containers. In case you predilute a sample before you reload it onto the analyzer, make sure to select the **Pre-dilution** check box on **Workplace** > **Test Selection**.

See *Prediluted samples* on page B-69.

Reruns with diluted samples

Tests that need to be rerun can be measured with normal, decreased, or increased sample volumes or with diluted samples.

	c 501 module, photometric unit	c 501 module, ISE unit	e 601 module
Decreased sample volume	✓	✓(a)	–
Increased sample volume	✓	–	–
Diluted sample	✓	–	✓

Table B-7 Availability of dilutions for reruns

(a) available only for urine samples as a manual rerun

These dilutions, performed by the analyzer, can either be programmed to be performed automatically, they can be requested manually by the operator or they can be requested by the Host.

Refer to the instructions for use of the respective application for recommended dilutions.

Priority of dilution ratio

If you choose a dilution ratio in the **S. Vol./D.Ratio** field on the **Workplace** > **Test Selection** screen, this selection will overwrite the pre-programmed dilution ratio indicated in the **Utility** > **Application** > **Analyze** screen.

If for example the test has a pre-programmed dilution ratio of 1:5 and you select a dilution ratio of 1:2 for **S. Vol./D.Ratio**, the test is processed with a dilution of 1:2.

Insufficient diluent volume on board

Insufficient diluent for a test entails the following:

- The test will not be masked on the **Test Selection** screen.
- The test with diluted sample will not be performed.
- No alarm will occur.
- An **M** (Mask Test) will be displayed for the test on the **Data Review** window.
- An **M** (Mask Test) will be displayed for the test on the **Data Monitor** report.
- The test without diluted sample will be performed.

Make sure that sufficient module-specific diluents are loaded for the analyzer to dilute samples.

Automatic dilutions

Individual tests can be configured with a dilution for the first run and/or rerun. Dilutions defined in the **cobas** 6000 software are automatically performed and calculated by the system. Administrator access is required to define these dilution parameters.

For more information, see:
Sample Volume area on **Utility** > **Application** screen (photometric tests)
Dilution ratios (e 601) on page B-262

Manually requested dilutions

Dilutions can be requested by the operator. Choose the **Sample Volume / Dilution** box on **Workplace** > **Test Selection** and select **Decrease**, **Increase**, or a dilution ratio (1:1, 1:2, …1:400).

For more information, see *Requesting a test manually* on page B-83.

Request from Host

Dilutions can also be requested by a Host computer. In this case, the samples are in the unloader and have to be reloaded and processed again.

Prediluted samples

Manually prediluted samples are samples which have been prediluted before they were put on the analyzer. (These are not to be confused with manually *requested* dilutions.)

Samples which have been manually prediluted can be measured, but the corresponding dilution factors are NOT taken into consideration when the results are calculated by the system. It is the operator's responsibility to calculate the final results.

For manually prediluted samples, make sure that you first select the **Pre-dilution** check box on **Workplace** > **Test Selection**. When the **Pre-dilution** check box is selected, results are flagged with *P* on the monitor report. The check mark is also visible in the **Pre-dilution** check box on **Workplace** > **Data Review** > **Test Review**. Predilution is also indicated in the results sent to the host.

Checking results

As results are generated on the instrument, they are saved in the database located on the internal hard disk of the control unit. When all results for all the tests requested for a sample are available, the analyzer sends them to the Host where they can be validated.

To view or edit results on the analyzer, use the **Workplace** > **Data Review** screen; all test results in the database are displayed here.

For more information, see:
Chapter 9 *Orders and results*
Data Review screen on page B-88
Archiving patient data on page B-91
Editing or deleting sample data on page B-93
Tracking samples on the analyzer on page B-98

When checking results, it can become necessary to locate a certain sample for further inspection. If a sample is still on the analyzer, use **System Overview** > **Sample Tracking** to locate it.

Sample tracking

The **Sample Tracking** window allows the operator to search for any sample on the analyzer from the moment of registration (the sample has passed the barcode reader) to the moment when the sample reaches the rack unloader (Tray 1).

The **Sample Tracking** window also allows the operator to search for samples and subsequently unload them.

The location of a sample is indicated by the **Sample Tracking** window only when the sample tray has not been removed from the unloader and no new run has been started yet.

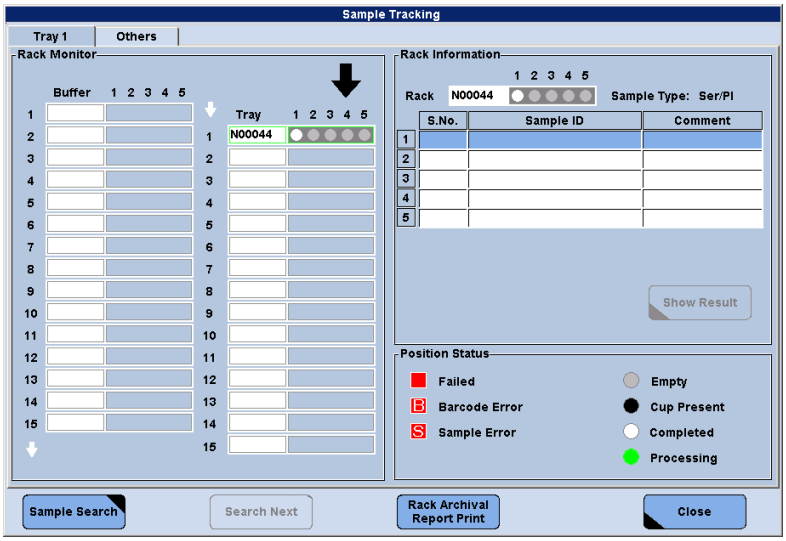


Figure B-40 Sample Tracking window

The **Sample Tracking** window has two tabs, the **Tray 1** tab and the **Other** tab.

Tray 1 tab

The **Tray 1** tab provides an overview of all racks in the unloader. The **Rack Information** area on the right side of the screen displays detailed information about each sample in the rack selected on the **Tray 1** tab.

Statuses displayed in the **Sample Tracking** window comprise the following:

	Failed	Measurement is completed and one or more results have a data alarm, or a test could not be processed.
B	**Barcode Error**	The barcode is unreadable (displayed in barcode mode only).
S	**Sample Error**	Possible reasons for sample error are: • Sample short • Air bubbles (only for **e** 601) • Sample clot
	Empty	The selected rack position is empty.
	Cup Present	A cup is present but no request has been made.
	Completed	The sample is completed with no flags.
	Processing	The sample is being processed.

For more information, see *Tracking samples on the analyzer* on page B-98.

Others tab

The **Others** tab provides information about racks and samples that are already registered by the analyzer (have passed the barcode reader) but have not yet reached the unloader.

In the **Others** tab the status *Cup present* is used instead of *Processing*, *Completed* or *Failed*.

For detailed information, see:
Tray 1 tab on page B-71
Tracking samples on the analyzer on page B-98

For more information, see *Sample Tracking window* on page E-17.

Printing sample information

Sample information in the database can be printed if necessary. The **Data Monitor/Report** displays all test information about a sample ID, tests performed and results measured, for example.

► To print a Data Monitor/Report report

1 Choose **Workplace** > **Data Review**.

2 Select a single sample, a range of samples or nonconsecutive samples to be printed from the sample list on the left side of the screen.

3 Choose **Print** (global button) > **Work Place**.

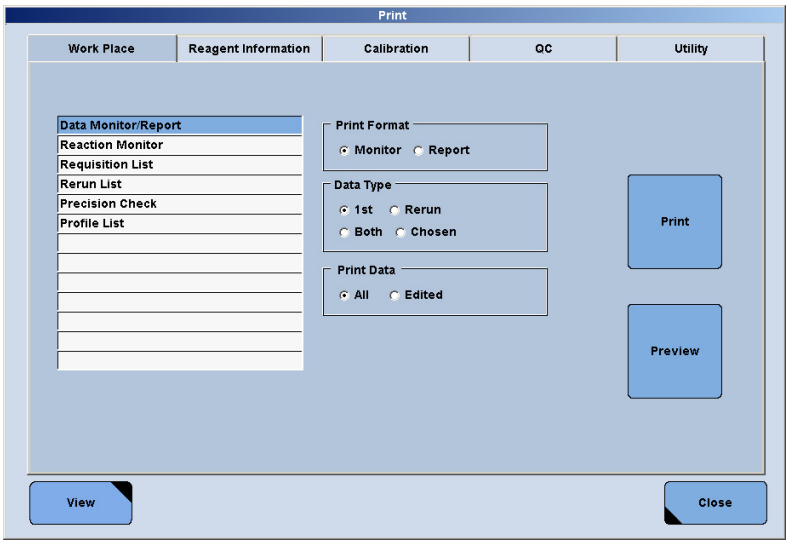


Figure B-41 Workplace Print screen

4 Choose **Data Monitor/Report** in the report list.

5 Select the desired print format, **Monitor** or **Report**, from the **Print Format** area.

Results with exception data alarms (**Utility** > **System** (**Page 4/4**) > **Review By Exception**) are not printed in the **Report** format.

For information on exception data alarms, see *Review By Exception window* on page E-419.

6 Select the appropriate result option, **1st**, **Rerun**, **Both** or **Chosen**, from the **Run Type** area.

7 Choose **All** in the **Print Data** area to print all results on the currently selected sample(s) or choose **Edited** to select printing of only edited results of the currently selected sample(s).

8 You can display the currently selected report on the screen without printing or you can print the report:

- To display a preview of the currently selected report, choose **Preview** and then **View**.
- To print the report, choose **Print**.

■

Sampling Stop

After all test requests are completed, sampling stops. After the last result is calculated, the analyzer remains in the **Rack Collect End** status for a set span of time. Thereafter, finalization for the **e** 601 is performed and then the entire analyzer goes into standby.

The span of time between operation and standby is specified under **Utility** > **System** (**Page 3/4**) > **Rack Delivery**. If the **Rack Reception Mode** check box is cleared, the analyzer goes into standby immediately after the last result is calculated.

For more information, see *Rack Reception Mode* on page B-284.

Shutting down the analyzer

This section discusses the tasks to be performed at the end of analysis. It gives a detailed description of the analyzer shutdown including both the complete shutdown and the sleep mode.

Maintenance before shutdown

At the end of routine operation, it is important that all required maintenance is performed. In addition to the routine daily maintenance, this could also include other scheduled maintenance—for example, weekly and monthly maintenance.

For information about maintenance items to be performed, refer to your laboratory maintenance schedule and see the following maintenance chapters:
Chapter 15 *General maintenance*
Chapter 17 *Maintenance c 501 with ISE*
Chapter 18 *Maintenance e 601*

Analyzer shutdown

After routine operation is finished and all required maintenance has been performed, the analyzer can be shut down. There are two options for the analyzer shutdown:

- Entering sleep mode
- The complete shutdown

Entering sleep mode provides the possibility of an automatic analyzer start-up on the next day. Thus, the analyzer can perform initialization in the absence of an operator, before the beginning of a working session. When the operator arrives, the analyzer is ready for operation.

For more information on automatic start-up, see *Start-up* on page B-31.

Perform one of the following procedures to shut down the analyzer after all required maintenance has been performed.

► To enter sleep mode

1 Check that sufficient reagents and auxiliaries are on board for the next start-up.

Choose the wake-up time and select any **Power Up pipe** function required (**Utility** > **System** (**Page 2/4**) > **Power Up Pipe Setting**).

See *Power Up Pipe function* on page C-15.

2 Choose **Shut Down** (global button) to display the **Shut Down** window.

3 Select the **Sleep** option and choose **Execute**. The **Sleep** window is displayed.

4 Select one of the following options:

- Select **Regulation** to let the system wake up at the preset time.
- Select **exception** and enter the date and time when the system should wake up.

The instrument is put in sleep mode until the wake-up time. The wake-up time is displayed.

5 Perform the regular checks after shutdown.

See *Checks after shutdown* on page B-76.

■

For **cobas** 6000 systems, the complete shutdown procedure should be performed at least once a week.

► To shut down the analyzer

1 Choose **Shut Down** (global button) to display the **Shut Down** window.

2 Select the **Shut Down** option, choose **Execute** and confirm the shutdown.

3 Wait until the computer power supply turns off. Then, switch off the power switch of the printer and monitor.

CAUTION! Damage to the control unit or data loss. Before switching-off of the analyzer, make sure the monitor indication has changed from shutdown to a state where nothing is displayed.

4 Switch off the operation power switch on the left side face of the rack sampler unit.

5 Turn off the water supply.

■

After shutting down the analyzer, check individual parts of the instrument according to the given maintenance recommendations.

See *Checks after shutdown* on page B-76.

Checks after shutdown

The checks and maintenance actions after shutdown correspond to the analyzer conditions that are to be checked before start-up.

See *Starting inspection* on page B-30.

Especially if the analyzer has been set for automatic start-up, it is important that the checks before start-up are done at the end of the previous working session; otherwise, problems may occur.

Laid out below is the list of analyzer conditions that are to be checked before start-up:

Control unit
- ☐ There is no floppy disk; CD or DVD in the corresponding drive.
- ☐ There is sufficient paper in the printer.

Core unit
- ☐ The water supply is switched on.
- ☐ Container for high concentration waste is empty.
- ☐ There are no racks on the rack loader, unloader, rack rotor, or conveyor line.

Analytic modules
- ☐ All surfaces are clean and clear of loose articles.
- ☐ No tubing is pinched or bent.
- ☐ Syringes are not leaking.
- ☐ Auxiliary reagents (cleaning solutions) required for start-up pipes are loaded.

***c** 501 module – ISE unit*
- ☐ All electrode cables and tubings are correctly connected. Tubing is not leaking.

***c** 501 module – photometric unit*
- ☐ All reagent cassettes are removed from the cassette disposal.
- ☐ Top cover is closed and locked.

***e** 601 module*
- ☐ The magazine door and drawer are closed.

Orders and results

This chapter provides descriptions of special tasks that are usually not part of the daily workflow. It is meant to complement the chapter Daily operation, where everyday tasks and common procedures for running the **cobas** 6000 analyzer are described.

In this chapter *Chapter* 9

Overview B-79
Test Selection screen B-80
Test selection matrix B-81
Colors B-81
Markings B-82
Requesting a test manually B-83
Entering unreadable sample barcodes B-86
Assigning or deleting a rerun rack manually B-87
Data Review screen B-88
Information on the screen B-89
Sample selection list B-89
Test results list B-90
Archiving patient data B-91
Editing or deleting sample data B-93
Displaying archived patient data B-95
Calib. Review screen B-96
Deleting a calibrator or a calibrated test B-97
Tracking samples on the analyzer B-98

Table of contents

Overview

The following sections describe tasks and data that can be accessed by the screens under the **Workplace** menu. The **Workplace** menu contains three screens: The **Workplace** > **Test Selection** screen, the **Workplace** > **Data Review** screen and the **Workplace** > **Calib. Review** screen.

However, this chapter does not cover all possible commands. For a complete description of all fields of the software's user interface, refer to the *Online Help*.

Workplace > Test Selection screen

Use this screen to enter test selections and demographics for a sample. The available fields for sample identification vary, depending whether STAT or routine test selections are being entered and whether the analyzer is operating in barcode mode or not.

For information on special operation procedures, see:
Requesting a test manually on page B-83
Entering unreadable sample barcodes on page B-86
Assigning or deleting a rerun rack manually on page B-87

Workplace > Data Review screen

Use this screen to perform tasks related to reviewing and editing routine and STAT results. Control results can also be viewed here. Other tasks that can be performed from this screen include editing demographic information, sending data to the Host, deleting data individually or in batches, backing up data and editing data.

For information on special operation procedures, see:
Archiving patient data on page B-91
Editing or deleting sample data on page B-93
Displaying archived patient data on page B-95
Tracking samples on the analyzer on page B-98

Workplace > Calib. Review screen

Use this screen to review the status of the calibrators that are currently processing and the status of the calibrations.

For information on special operation procedures, see *Deleting a calibrator or a calibrated test* on page B-97.

Test Selection screen

To display this screen, choose **Workplace** > **Test Selection**.

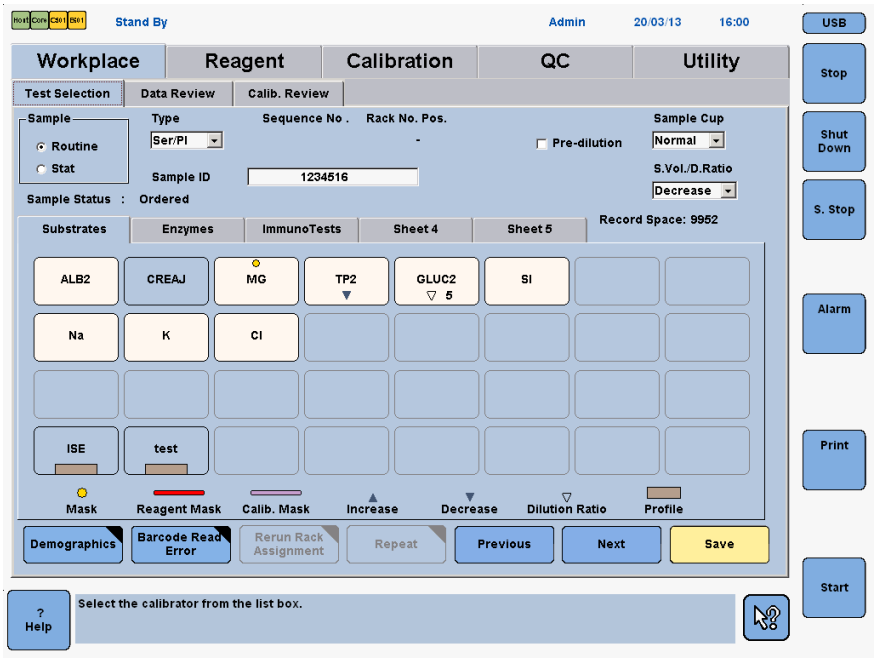


Figure B-42 Test Selection screen

Use this screen to manually enter test selections and demographics for a sample. The available fields for sample identification vary, depending whether STAT or routine test selections are being entered and whether the analyzer is operating in barcode mode or not.

Fields	Barcode mode		Non-barcode mode	
	Routine	Stat	Routine	Stat
Sequence No.	–	–	✓	–
Rack No. / Pos.	–	–	–	✓
Sample ID	✓	✓	✓	–

Table B-8 Test Selection screen - available fields for sample identification

If test selections are downloaded from a Host, this screen is commonly not used.

For information, see:
Test selection matrix on page B-81
Requesting a test manually on page B-83
Entering unreadable sample barcodes on page B-86
Assigning or deleting a rerun rack manually on page B-87

Test selection matrix

A maximum of 160 test keys can be programmed on the system. The test matrix has 32 keys in each group and up to 5 groups of test keys can be programmed on **Utility** > **System** (**Page 1/4**) > **Key Setting**. One group at a time is displayed on the **Test Selection** screen. Use the tabs above the test matrix to switch between the groups. Group names are defined on **Utility** > **System** (**Page 1/4**) > **Key Setting**.

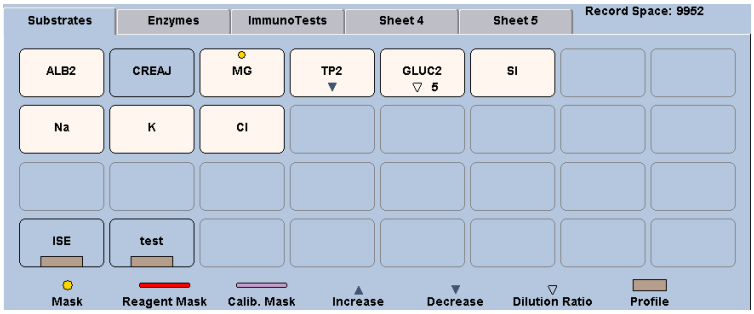


Figure B-43 Test matrix

Colors

The test keys display different colors to indicate the status of the test for the sample ID in the **Sample ID** text box. The following colors are available:

This test has been selected.

This test has been performed, a result is available, and can be ordered again.

A rerun has been performed for this test and the result is available.

Markings

One test or profile can be assigned to each key. The test keys display special markings depending on the test's status or programming. The different markings and their meanings are outlined below:



Blank test key indicates no test is assigned.



Test key with a test or profile name and no masking indicators can be requested, further settings are not required. The reagent is on board and registered.



Mask

- Test manually masked on the **Masking** window (**Start** (global button) > **Masking**, **P**- or **T**-**mask** on all measuring cells for **e** 601)
- All modules which have this test on board are deactivated

The test can be requested. However, the test is performed only after the test is manually unmasked

Reagent Mask (no reagent available)

Test is automatically masked by the system. The volume of a reagent (**cobas c** pack or **cobas e** pack), or detergent cassette, that is required for the respective test is either insufficient or the reagent is not present on the analyzer. The test can be requested.

c 501: If a diluent **cobas c** pack or other wash solutions are empty or missing (Sample Cleaner 1, Sample Cleaner 2, or ProbeWash), the corresponding reagent is **not** masked.

e 601: If the necessary diluent or pretreatment are empty or missing, the corresponding test is masked.

Calib. Mask (calibration failed)

Test is automatically masked by the system due to a failed or missing calibration.

The purple bar will not be displayed on the test key if:

- Calibration auto masking setting for the individual test is not selected on **Utility** > **Application** > **Calib**.
- Calibration auto masking setting for the analyzer is not selected on **Utility** > **System** (**Page 2/4**) > **Calib Mask Setting**.



Increase (**c** 501)

Test will run with an increased sample concentration as set on the **Utility** > **Application** > **Analyze** screen.

The symbol disappears as soon as the result is generated.



Decrease

Test will run with a decreased sample concentration as set on the **Utility** > **Application** > **Analyze** screen.

The symbol disappears as soon as the result is generated.



Dilution Ratio

Test will run with a dilution. The number after the triangle indicates the dilution factor (for example, 2 indicates a 1:2 dilution).

The symbol disappears as soon as the result is generated.



Profile

A brown bar on the key indicates the key has been assigned a profile. When selected, all tests assigned to that profile are highlighted.

Requesting a test manually

Tests can be manually selected for STAT and routine samples when the analyzer is in either barcode or non-barcode mode.

- Application-specific dilutions are performed automatically by the system.
- Not all dilution ratios are available.
- If you choose a dilution ratio in the **S. Vol./D.Ratio** field, this selection will overwrite the pre-programmed dilution ratio indicated in the **Utility** > **Application** > **Analyze** screen.
 If for example the test has a pre-programmed dilution ratio of 1:5 and you select a dilution ratio of 1:2 for **S. Vol./D.Ratio**, the test is processed with a dilution of 1:2.
- For **c** 501, if the sample volume of a test is higher than 20 µL, a manually requested dilution is not accepted and a pop-up window is displayed.
- The **e** 601 cannot pipette increased sample volume.
- For **e** 601 assays there is a recommended dilution described in the instructions for use. Only these dilutions should be used.

All manual selections such as sample type and dilution ratio remain as selected, within and between samples, until they are manually reset.

Micro cups are not to be used on the **e** 601.

► To request a routine sample

1. Choose **Workplace** > **Test Selection**.
2. Select the sample type.

 Only the available tests for the corresponding sample type are displayed in the test matrix.
3. Select the **Routine** option from the **Sample** area on the top left of the **Test Selection** screen.
 - In non-barcode mode the cursor moves to the **Sequence No.** text box. Go to step 4.
 - In barcode mode the cursor moves to the **Sample ID** text box. Go to step 5.
4. Type in the sequence number for the sample in the **Sequence No.** text box and press <Enter>. The cursor moves to the **Sample ID** box.
5. Type in the sample ID of the sample in the **Sample ID** box and press <Enter>. The cursor moves to the **Pre-dilution** check box.
6. Select this check box if the sample has already been diluted and press <Enter>. The cursor moves to the **Sample Cup** box.
7. Select the sample container type and press <Enter>. The cursor moves to the **Sample Volume / Dilution** box.
8. Select the necessary dilution, if any, for the sample and press <Enter>. The cursor moves to the test key matrix.
9. Select the test, combination of tests or test profiles for the sample. Selected tests and profile keys appear white.
10. Choose **Save** to save the test selection.

■

► To request a STAT sample

1. Choose **Workplace** > **Test Selection**.
2. Select the sample type.

 Only the available tests for the corresponding sample type are displayed in the test matrix.
3. Select the **Stat** option from the **Sample** area on the top left of the **Test Selection** screen.
 - In non-barcode mode the cursor moves to the **Rack ID** text box. Go to step 4.
 - In barcode mode the cursor moves to the **Sample ID** text box. Go to step 6.
4. Type in the rack ID of the sample in the **Rack ID** text box and press <Enter>. The cursor moves to the **Pos.** text box.
5. Type in the position number of the sample in the **Pos.** text box and press <Enter>. The cursor moves to the **Sample ID** text box.
6. Type in the sample ID of the sample in the **Sample ID** text box and press <Enter>. The cursor moves to the **Pre-dilution** check box.
7. Select the **Pre-dilution** check box if the sample has already been diluted and press <Enter>. The cursor moves to the **Sample Cup** box.
8. Select the sample container type and press <Enter>.

 The cursor moves to the **Sample Volume / Dilution** box.
9. Select the necessary dilution, if any, for the sample and press <Enter>. The cursor moves to the test key matrix.
10. Select the test, combination of tests, or test profiles for the sample. Selected tests and profile keys appear white.
11. Choose **Save** to save the test selection.

■

Entering unreadable sample barcodes

⚠ CAUTION

Incorrect results due to sample mismatch

If samples with unreadable barcodes are entered manually, sample mismatch may occur.

- When registering samples with unreadable barcodes, make sure to select the correct sample. Check the rack and position number of the affected sample.

The **Barcode Read Error** screen is only available in barcode mode.

► To enter a samples with unreadable barcode

1 Choose **Workplace** > **Test Selection**.

2 Choose **Barcode Read Error**.

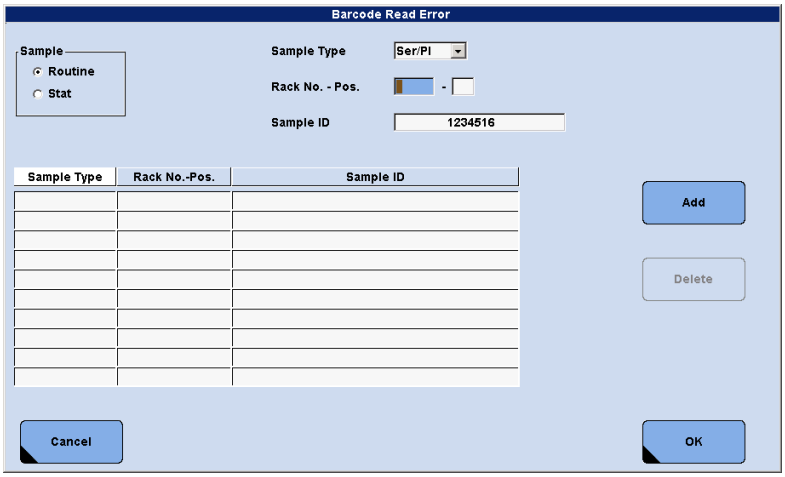


Figure B-44 Barcode Read Error window

3 Select the sample type (**Stat** or **Routine**) in the **Sample** area and press <Enter>.

4 Select the sample material from the **Sample Type** list box and press <Enter>.

5 Type the rack no. and position in the **Rack No.-Pos.** text boxes and press <Enter>.

6 Type the sample ID of the sample in the **Sample ID** text box and press <Enter>.

7 Choose **Add**. The sample type, rack number and position, and sample ID are displayed.

8 Repeat steps 3 to 7 for any further samples with a barcode read error.

9 Choose **OK**.

■

The non-read position assignments are deleted once the rack(s) to which samples are assigned are scanned by the rack ID reader. Therefore, once the rack is read it can be re-used for different samples. If it is necessary to run these samples again, the position assignment must be re-entered if the barcode has not been replaced.

Assigning or deleting a rerun rack manually

Samples requested for a rerun are only manually assigned to a rack when the analyzer is in non-barcode mode. Use the pink rerun racks for reruns in non-barcode mode.

► To assign a rerun rack

1 Choose **Workplace** > **Test Selection**.

2 Type the sample ID of the sample in the **Sample ID** text box or type the sequence number of the sample in the **Sequence No.** text box.

If any changes have to be made to the test selection and/or sample dilution, they can be done at this time.

3 Choose **Rerun Rack Assignment** to display the **Rerun Rack Assignment** window.

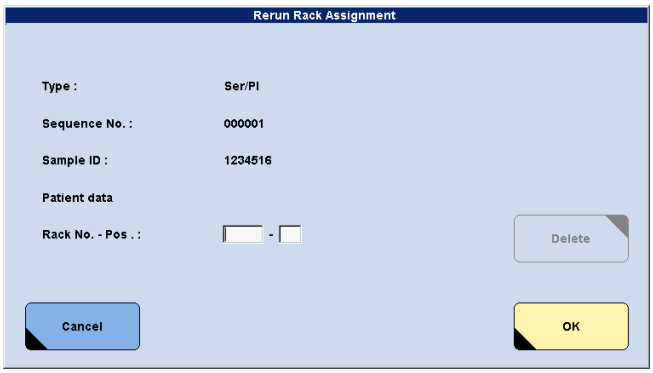


Figure B-45 Rerun Rack Assignment window

4 Check that the details displayed on the **Rerun Rack Assignment** window are correct.

5 Type the rack No. and position of the pink rerun rack in the **Rack No.-Pos.** text boxes.

6 Choose **OK**.

■

► To delete a rerun rack

To reassign a rerun, the old assignment must be first deleted, and then the new rack ID and position entered.

1 Select the sample that you need to reassign from **Workplace** > **Test Selection**.

2 Choose **Rerun Rack Assignment**.

3 Choose **Delete** to delete the rack assignment after confirmation.

4 Choose **Cancel** to close the **Rerun Rack Assignment** window.

■

Data Review screen

To display this screen, choose **Workplace** > **Data Review**.

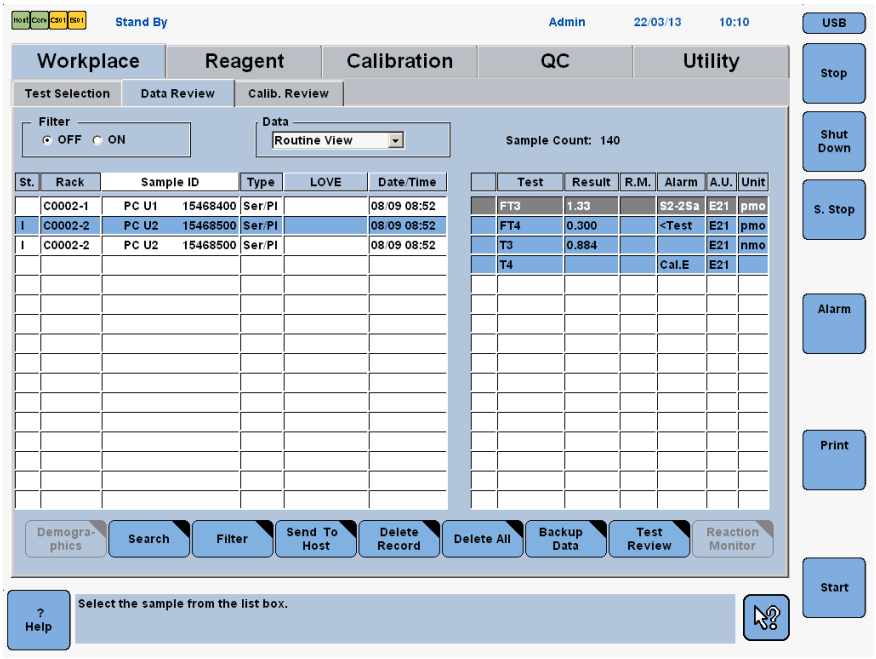


Figure B-46 Data Review screen (barcode mode)

Use this screen to perform tasks related to reviewing and editing routine and STAT results. Control results can also be viewed here.

Other tasks that can be performed from this screen include editing demographic information, sending data to the Host, editing, searching, filtering, and deleting data individually or in batches, and backing up data.

For information on special operation procedures, see:
Archiving patient data on page B-91
Editing or deleting sample data on page B-93
Displaying archived patient data on page B-95
Tracking samples on the analyzer on page B-98

Information on the screen

This section describes the information on the **Data Review** screen.

Sample selection list

The list on the left side of the screen displays the patient and control samples registered by the system. Its content varies depending on whether barcode mode, or non-barcode mode is selected on **Utility** > **System**.

The St. column displays the sample status codes:

O (Ordered)	Sample registered by user or Host.
P (Processing)	Sample ID or rack ID has been read by barcode reader.
I (Incomplete)	Samples processed, but a data alarm is present.
No symbol (Complete)	Sample successfully processed. All test results are available without a data alarm.
H (Sent to Host)	Sample results have been sent to the Host.
#	Sample has been pipetted on ISE or **c** 501. Note that additional measurements on the **e** 601 might be affected by carryover (see following note).
b	Sample has been processed on **c** 501. A special wash for the sample probe of the **c** 501 has been performed before the sample was pipetted.

Possible sample carryover when measuring high-priority elecsys (HPE)

If HPE tests are requested for a sample, this sample is pipetted on the **e** 601 module prior to pipetting on **c** 501 module.

If a sample has already been processed on the **c** 501 module, a #-flag is displayed on the **Data Review** screen. This indicates the risk of potential carryover if sample from this sample container is used for additional or rerun HPE requests.

- If a #-flag is displayed, always use newly aliquoted samples to perform manual reruns of HPE tests.

For more information about special washes, see:
Programming a special wash for c 501 modules on page B-297
Programming a special wash for e 601 modules on page B-304

For control samples only the following statuses are available: **P**, **I**, **H** and no symbol (complete).

Test results list

The list on the right side of the screen displays the results of the tests performed on the sample currently selected in the sample selection list. The results are displayed in this **Test Result** list as soon as they are available.

A symbol for the volumes to be used is displayed to the left of the **Test** column.

The symbols for the volumes disappear as soon as the result is generated. Information about the sample concentration (dilution ratio) is still displayed in the **Test Review** window.


(Dark blue): Indicates a test to be run with normal sample concentration.


(Dark blue): Indicates a test is marked to be run with an increased sample concentration. This applies to photometric assays (**c** 501 module) only.


(Dark blue): Indicates a test is marked to be run with a decreased sample concentration. This applies to photometric assays and ISE tests (**c** 501 module) only. For ISE tests only urine samples can be run with decreased volume.


(White): Indicates a test is marked to be run with a diluted sample.

\# A hash (#) indicates a sample with potential sample carryover. This sample has been processed on a **c** 501 in the first run. In a possible second run a test is requested which would have required a special wash for the sample probe of the **c** 501 module. The hash (#) appears as a warning for a potential sample carryover together with the *Samp.O* alarm.

If an add-on test is ordered for a sample it is displayed as ordered and a blue square in the first column to the left of the **Test** column is displayed.

The **R.M.** column displays a result message. Reactive (**r**), non reactive (**n**) or borderline (**b**) indicates if a test for a qualitative assay has a positive, negative or borderline result, respectively.

The **A.U.** column displays the analytical unit (analytical module) for the test of the selected sample.

Results <Test

In case the **Suppress Result <Test** (**Utility** > **System** > **Alarm** (**Page 1/4**)) is activated and the measurement result is below the technical limit, the lower limit of the technical limit is displayed as the result flagged with a data alarm. The displayed data alarm depends on the data alarm priority.

For information on the data alarm priority, see *Data alarm priority* on page D-8.

Number of runs

Please note the number of runs (1st., Rerun) is test-oriented, not sample-oriented.

If a test has already run twice and a third request is made, the result of the second run is replaced by the result of the third run. An additional run (3rd., 4th., and so on) is only possible, if the previous result has been uploaded to the Host and the **3rd Results Acceptance** checkbox (**Utility** > **System**) is enabled.

If Host communication is not available, it is not possible to use **3rd Results Acceptance**.

For more information about **3rd Results Acceptance**, see *Generating multiple results for a single test* on page B-280.

Archiving patient data

Patient data can only be archived when the system is in standby.

► To archive patient data

1 Choose **Workplace** > **Data Review**.

2 Select the samples for which data is to be backed up from the list on the left of the **Data Review** screen.

3 Choose **Backup Data** to display the **Backup Data** window.

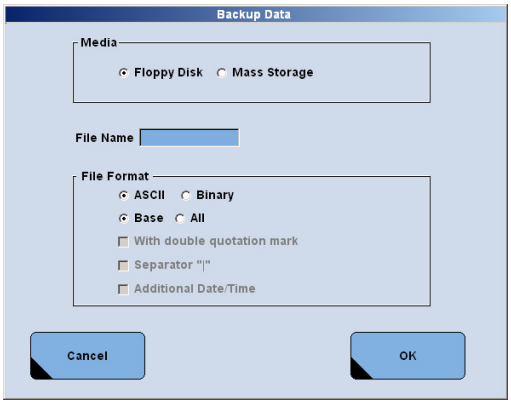


Figure B-47 Backup Data window

4 Select the medium to which the data will be written, for example **Floppy Disk**, from the **Media** area.

Option	Description
Floppy Disk	Select this option to write the data to a floppy disk.
Mass Storage	Select this option to write the data to a mass storage. If a **USB** storage device is inserted, the instrument uses the USB as mass storage. If no USB storage device is inserted, the instrument uses a DVD disk as mass storage.

Table B-9 Media area

5 Insert the chosen medium into the corresponding disk drive.

6 Type the name to be given to the file in the **File Name** text box.

7 Select the format in which the data is to be written, **ASCII** or **Binary**, and select **Base** or **All** option in the **File Format** area.

- ASCII files can be read by other PC systems, but cannot be reloaded in to the **cobas** 6000 system.
- Binary files can be reloaded in to the **cobas** 6000 system but cannot be read by other PC systems.
- When the **Base** option is selected, no data from **e** 601 tests are saved.

8 Choose **OK** to back up the selected data after confirmation. The **Save Data** window is displayed. This closes after the data has been backed up.

If a confirmation window with the message *Mass storage media is full or Floppy disk is full* is displayed during backup, no data is stored on the media.

Insert an empty medium and repeat the backup process

■

For more information about the different backup options, see *Backup Data window* on page E-230.

For more information on using DVD disks, see *Preparing a DVD disk* on page B-244.

Editing or deleting sample data

Sample data displayed on the **Data Review** screen can be edited or deleted if required. Use the following procedures to edit or delete sample data.

► To select a result to be edited or deleted

1 Choose **Workplace** > **Data Review**.

2 Select **Routine View** from the **Data** list box.

QC View is also available as an option in the list box in the **Data** area, but this view displays only QC data.

For information on using a **Backup Disk**, see *Displaying archived patient data* on page B-95.

3 Select a sample from the list on the left of the screen. The results, 1st and Rerun, of the tests performed on this sample are displayed in the list on the right of the screen.

4 Choose **Test Review** to display the **Test Review** window. This window displays more information on the test results.

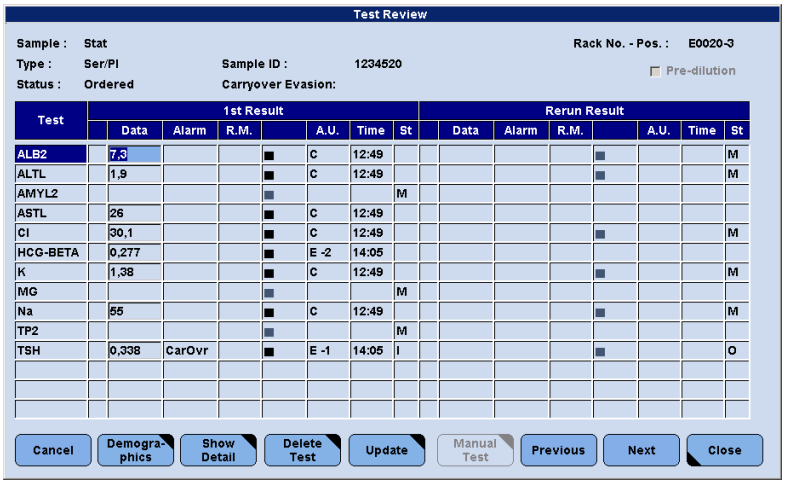


Figure B-48 Test Review window

5 Select the test result in the **Data** column. The result is activated (blue background) and highlighted white.

■

The **St.** column displays the status code of the test result.

O (Ordered)	Test requested by user or Host.
P (Processing)	Sample ID or rack ID has been read by core.
I (Incomplete)	Test processed, but a data alarm is present.
No symbol (Complete)	Test successfully processed.
H (Sent to Host)	Test results have been sent to the Host.
M (Masked Test)	Test has been masked due to an abnormality during processing. Displayed only on **Workplace** > **Data Review** > **Test Review**.
	Test has not been performed due to missing dilution. However, a test request without dilution will be performed and the test is not masked on the **Workplace** > **Test Selection** screen.
E (Edited Test)	Test results have been manually edited on **Workplace** > **Data Review** > **Test Review**.

The status of Ordered, Masked and Edited Test is not applied to control samples.

► To edit sample data

1 Select the test result to be edited.

2 Enter the new result (the old result is overwritten) and press <Enter>. The **Updated** button turns yellow.

3 Choose **Update** to save the changes or **Cancel** to reset the entry to the original value.

■

Edited test results are flagged with an *Edited* data flag.

► To delete sample data

1 Select the test result to be deleted.

2 Choose **Delete Test** to delete the test after confirmation.

■

► To delete a sample from the Data Review screen

1 Choose **Workplace** > **Data Review**.

2 Select an individual sample, or a number of samples, to delete from the list on the left of the screen.

3 Choose **Delete Record** to delete the sample(s) selected after confirmation.

■

The **Sample Count** is unchanged after a record has been deleted. To delete all records, use **Delete All**. This will reset the sample count to 0.

Displaying archived patient data

Only data saved in binary format can be reloaded onto the analyzer.

Archiving patient data on page B-91

Reloaded data can only be viewed on the **Data Review** screen.

► To display archived patient data

1 Select **Backup Disk** from the **Data** list box on the **Workplace** > **Data Review** screen to display the **Read Back Up Disk** window.

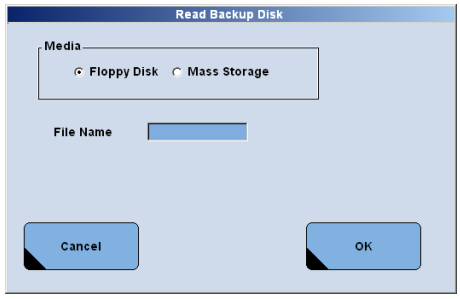


Figure B-49 Read Backup disk window

2 Select the medium from which the data will be read, for example **Floppy Disk**, from the **Media** area.

If only one medium is available, for example, floppy disk, the **Media** area is not active.

3 Insert the chosen medium into the corresponding disk drive.

4 Type the file name in which the data is saved in the **File Name** text box.

5 Choose **OK**. The saved data is displayed on **Workplace** > **Data Review**.

■

Calib. Review screen

To display this screen, choose **Workplace** > **Calib. Review**.

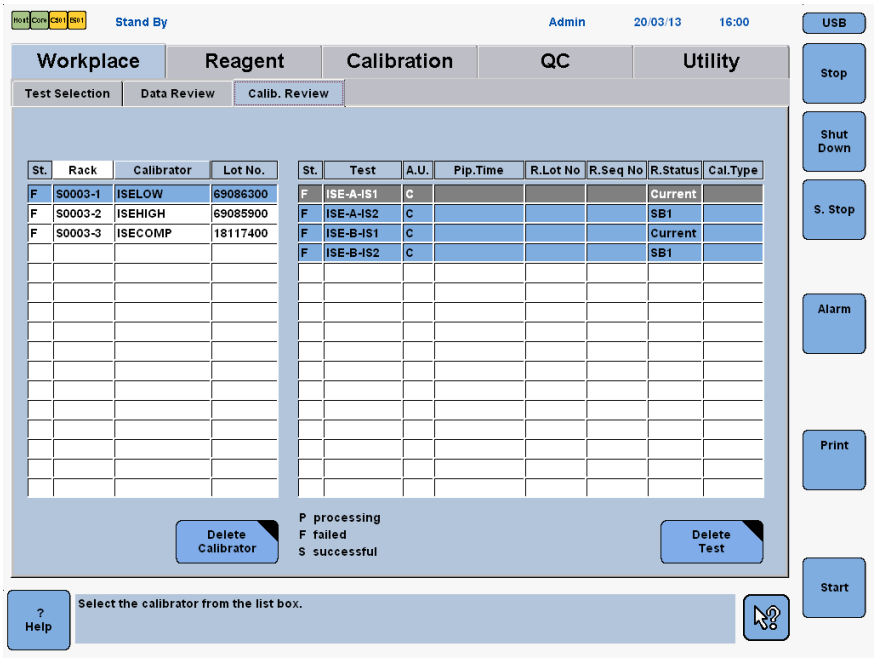


Figure B-50 Calib. Review screen

Use this screen to review the status of the calibrators that are currently processed and the status of the calibrations.

For information on special operation procedures, see *Deleting a calibrator or a calibrated test* on page B-97.

Calibrator selection list

The list on the left side of the screen displays the calibrators registered by the analyzer.

The **St.** column displays the calibrator status codes:

P (Processing)	The calibrator is registered by the analyzer (barcode is already read).
F (Failed)	At least one of the calibrations performed with this calibrator could not generate a valid calibration.
S (Successful)	Calibrator successfully processed. All calibrations performed with this calibrator have generated valid calibration results.

Test results list

The list on the right side of the screen displays detailed information for the tests performed with the calibrator currently selected in the calibrator selection list.

The **St.** column displays the calibration status codes:

P (Processing)	The calibrator for the test is registered by the analyzer (barcode is already read) and at least one calibration is requested for this calibrator. If the calibrator has already been pipetted by the analyzer, a pipetting date and time is available.
F (Failed)	No valid calibration has been generated for the test.
S (Successful)	A valid calibration has been generated for the test.

For more information about the calibration status, see *Calibration Status screen* on page B-166.

Deleting a calibrator or a calibrated test

Calibrator data displayed on the **Calib. Review** screen can be deleted if required during operation. Use the following procedures to delete the status of a calibrator or a test. If you start the system from stand by this screen is reset and all information is deleted.

► To delete a calibrator

1. Choose **Workplace** > **Calib. Review**.
2. Select a calibrator, to delete from the list on the left of the screen.

 The calibrator is highlighted in blue.
3. Choose **Delete Calibrator** to delete the calibrator after confirmation.

■

► To delete a test (c 501)

1. Choose **Workplace** > **Calib. Review**.
2. Select a test, to delete from the list on the right of the screen.

 The calibration test is highlighted in blue.
3. Choose **Delete Test** to delete the calibration test after confirmation.

■

Tracking samples on the analyzer

The **Sample Tracking** window allows the operator to search for any sample on the analyzer from the moment of registration (the sample has passed the barcode reader) until the moment the sample is removed from the rack unloader (**Tray 1**) and no new run was started.

See *To track a sample on the analyzer* on page B-98.

The **Sample Tracking** window also allows the operator to search for samples and subsequently unload them.

See *To unload specific racks* on page B-100.

Only STAT and routine samples

Only STAT and routine samples can be searched for in the **Sample Tracking** window.

To track a sample on the analyzer

1 Choose **Sample Tracking** on the **System Overview** screen.

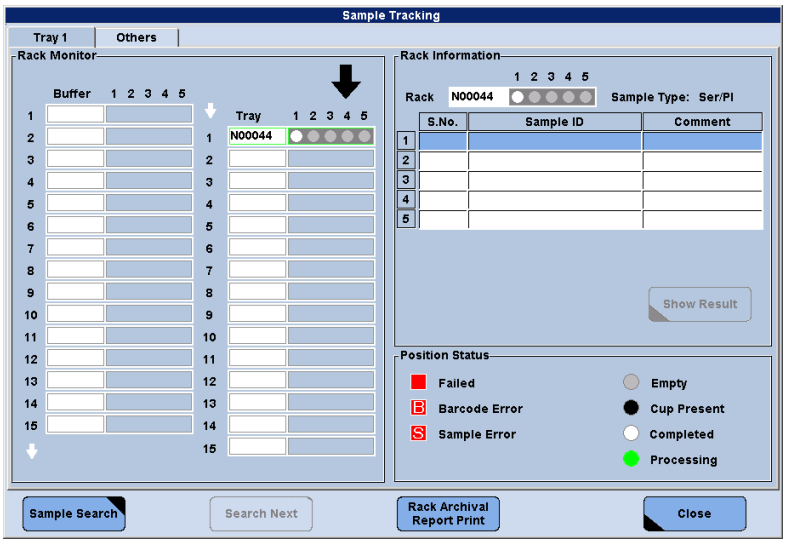


Figure B-51 Sample Tracking window

2 Choose **Sample Search** to display the **Sample Search** window.

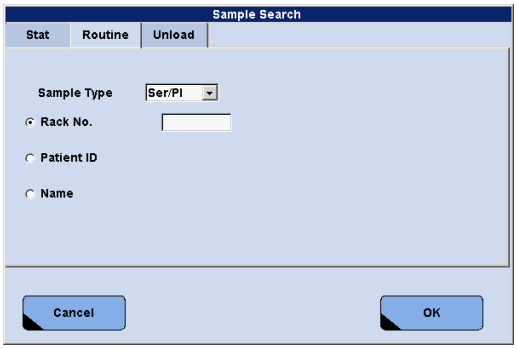


Figure B-52 Sample Search window - barcode mode

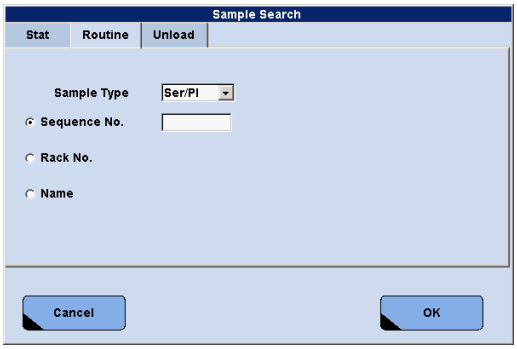


Figure B-53 Sample Search window - non-barcode mode

- If searching for a STAT sample choose the **Stat** tab.
- If searching for a routine sample choose **Routine**.

For using the **Unload** tab, see *To unload specific racks* on page B-100.

3 Choose the sample type.

4 Select the required search criterion.

5 Enter the data you are searching for in the corresponding text field.

6 Choose **OK**.

- If the sample is in the Unloader the sample is highlighted in the **Rack Information** area and the rack is highlighted in the **Rack Monitor** area.
- If the sample is not in the Unloader a short message is displayed under the **Others** tab indicating the location of the sample.

■

The **Others** tab shows samples that are being processed, but are not yet unloaded. Thus, it can only show information when the analyzer is in Operation mode.

For more information, see:
Sample tracking on page B-70
Sample Tracking window on page E-17

► To unload specific racks

1 Choose **Sample Tracking** on the **System Overview** screen.

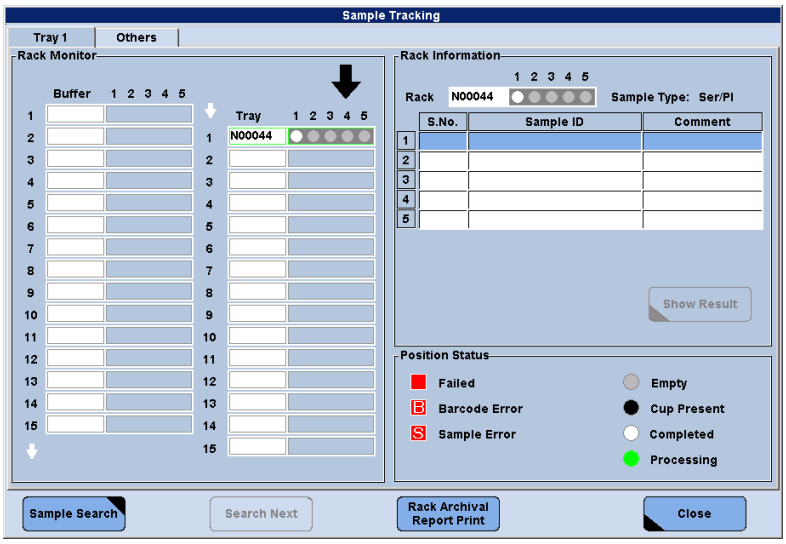


Figure B-54 Sample Tracking window

2 Choose **Sample Search** > **Unload**.

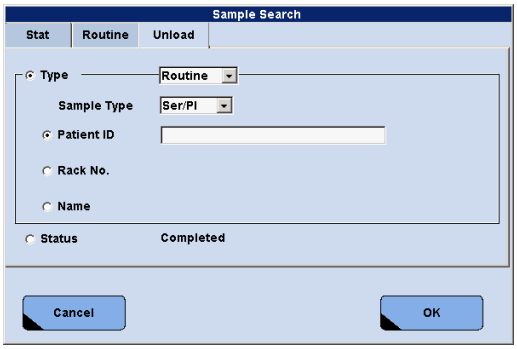


Figure B-55 Sample Search window - barcode mode

The **Unload** tab can be used to search for specific routine or STAT samples to be unloaded.

3 Select the required option, **Type** or **Status**.

- Select **Type** to search for samples according to the criteria in the **Type** area (for example, **Sample Type**, **Patient ID**, **Rack No.**).
- Select **Status** to search for samples with a specific sample status. Possible statuses are: **Completed**, **Failed**, **Barcode Error**, **Sample Error**

4 Select the required search criteria.

5 Enter the data you are searching for in the corresponding text field.

6 Choose **OK**.

A list of racks that meet the search criteria is displayed in the **Rack Monitor** area of the **Sample Tracking > Others** window.

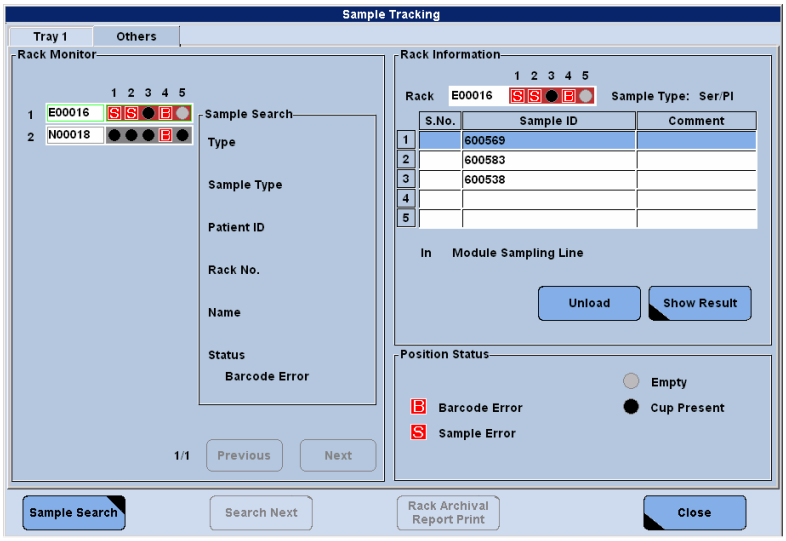


Figure B-56 Sample Tracking window - search results

7 Select the rack to be unloaded.

8 Choose **Unload** in the **Rack Information** area and confirm the unloading process.

The rack is transferred to the rack unloader.

- If the rack is in the pipetting position, on the module rack buffer (**e** 601) or already scheduled to one of the modules pipetting of all samples on the rack will be finished, before the rack is transferred to the rack unloader.
- Only routine and STAT racks can be unloaded, no calibrator and QC racks.
- A STAT rack can only be unloaded after it was processed once at any module.
- If a rack is unloaded after pipetting, the result for the samples will be processed.

■

For more information, see:
Sample tracking on page B-70
Sample Tracking window on page E-17

Reagents

This chapter describes all types of reagents used on the **cobas** 6000 analyzer series. It provides information about the system's reagent management as well as detailed information on how the operator can monitor the status of loaded reagents (operator-related reagent management).

In this chapter *Chapter* 10

Reagent concept – c 501 B-105
Reagents for ISE applications B-105
Overview of reagents for ISE B-105
Reagents B-106
Calibrators B-107
Controls B-107
Auxiliary reagents B-107
Reagents for photometric applications B-108
Overview of reagents for photometric unit B-108
Reagents B-108
Diluents B-110
Calibrators and controls B-110
Auxiliary reagents B-111
Reagent concept – e 601 B-114
Reagents for immunoassay B-114
Overview of reagents for immunoassays B-114
Reagents B-115
Pretreatments and the PT link function B-118
Diluents B-120
Calibrators and controls B-122
Auxiliary reagents B-122
Operator-related reagent management B-124
Reagent Setting screen B-125
Manual reagent registration B-126
Loading and unloading of reagent cassettes (c 501) B-127
Reagent reloading (e 601) B-128

Reagent Status screen B-130
Replacing auxiliary reagents (c 501) B-131
Replacing auxiliary reagents (e 601) B-132
Replacing empty auxiliary reagents B-132
Replacing auxiliary reagents when not empty (green light is not flashing) B-135
Replacing consumables and emptying solid waste (e 601) B-139
Reagent Overview button B-141
Reagent Overview c 501 module B-141
Reagent area B-142
Inventory area B-144
ISE area B-145
Detail window B-146
Reagent Overview e 601 module B-147
Reagent area B-148
Inventory area B-149
Detail window B-150
Inventory Update window B-151

Reagent concept – c 501

This section provides information about reagents used on the **c** 501 module and how they are used for ISE applications and photometric applications. It describes the corresponding reagent containers used and explains how the system registers new reagents and how it monitors reagent consumption.

Reagents for ISE applications

This section describes all reagents that are necessary to run the **c** 501 module's ISE unit.

The following ISE applications are available:

- Na^+: Sodium serum/plasma and urine
- K^+: Potassium serum/plasma and urine
- Cl^-: Chloride serum/plasma and urine

Overview of reagents for ISE

The **c** 501 module's ISE unit uses the following reagents:

- *Reagents*
- *Calibrators*
- *Controls*
- *Auxiliary reagents*

Reagents

Each ISE measurement uses the following reagents:

Product name	Short name[(a)]	Description	Containers on the analyzer	Location
ISE Internal Standard	ISE IS	One-point calibrations performed before and after each sample measurement	2 bottles of 600 mL	ISE reagent compartment
ISE Diluent	ISE Dil.	1:31 dilution of sample	2 bottles of 300 mL	
ISE Reference Electrolyte	ISE Ref.	Reference electrode measurements	1 bottle of 300 mL	

Table B-10 Reagent for ISE measurement

(a) used in this documentation

ISE reagent container

The ISE IS, ISE Ref., and ISE Dil. bottles are positioned in the ISE reagent compartment. ISE reagent bottles do not use a barcode for registration.

A bottle insert can be used to prevent evaporation of the ISE IS.

ISE reagent volume

At analyzer startup, the remaining volume is checked for the current bottle of ISE IS, ISE Ref., and ISE Dil..

There is a bottle sensor at each of the reagent positions of the ISE reagent compartment. By means of a light beam, the sensor detects the presence of a reagent bottle. In addition to this, the ISE pipetter probe is equipped with a level detector (capacitance method), which monitors the liquid level in the reagent bottles.

ISE reagent replacement

A green indicator lamp (next to the reagent position) lights up if no reagent bottle is present or if the liquid level falls below the limit where the bottle needs to be replaced. For ISE IS and ISE Dil., the analyzer performs an automatic bottle changeover when a reagent shortage is detected.

Thus, replacement of ISE IS and ISE Dil. reagent bottles can be performed regardless of instrument status. ISE Ref. is to be replaced only when the analyzer is in standby or if the **c** 501 module is masked and in standby. After replacement of ISE Ref., a **Reagent Prime** is required.

When the number of available tests is “0” as a sum of the remaining volumes in two bottles, all ISE tests will be masked and thus no subsequent measurement is possible.

When you replace an ISE reagent bottle, always use new bottles.

For instructions on how to replace ISE reagents, see *c 501 – ISE unit* on page B-45.

Calibrators

The **c** 501 module´s ISE unit uses multi-analyte calibrators. The same multi-analyte calibrator is used for all ISE applications.

Barcode Calibrators can be used either with or without barcodes. If necessary, change the corresponding settings (**Barcode Setting** area on **Utility** > **System**).

Hints on using barcoded and non-barcoded calibrators

Do not use barcoded and non-barcoded calibrator vials on the same rack.

If working with non-barcoded calibrators, correct position of the calibrators must be checked, otherwise incorrect measurement results may occur.

If working with barcoded calibrators, you still have to assign the calibrators on any other calibrator rack using the codes 502, 503, and 763. The system will not start without this.

The order on the calibrator rack must be S1 (ISE Low), S2 (ISE High), S3 (ISE High).

Calibration interval The calibration interval for all ISE applications must not exceed a 24 hour time period.

For more information about ISE calibration, see:
Calibration concept - ISE applications on page B-159
ISE calibration on page B-193

Controls

The **c** 501 module´s ISE unit uses multi-analyte controls. The same multi-analyte control is used for all ISE applications.

Barcode Quality controls can be used either with or without barcodes. If necessary, change the corresponding settings (**Barcode Setting** area on **Utility** > **System**).

Hints on using barcoded and non-barcoded controls

Do not use barcoded and non-barcoded control vials on the same rack.

If working with non-barcoded controls, correct position of the controls must be checked, otherwise incorrect measurement result may occur.

Auxiliary reagents

The **c** 501 module´s ISE unit uses the following auxiliary reagents. The auxiliary reagents are used daily by the green wash rack maintenance procedure.

Product name	Short name[a]	Description	Containers on the analyzer	Location
Sample Cleaner 1	SmpCln 1	Washing the sample probe	Sample tube or cup on green wash rack[b]	Rack Pos. 1
ISE Cleaning Solution	SysClean	Washing the ISE flow path		Rack Pos. 2
Activator	Activator	Conditioning the ISE electrodes		Rack Pos. 3

Table B-11 Auxiliary reagents for ISE

(a) used in this documentation and in the software

(b) Hitachi micro cups, non-standard and false bottom tubes must not be used for the ISE green wash rack solutions.

For information on processing the green wash rack, see *Processing green wash rack* on page C-69.

Reagents for photometric applications

This section describes all reagents necessary to run the **c** 501 module's photometric unit.

Overview of reagents for photometric unit

The **c** 501 module´s photometric unit uses the following reagents:

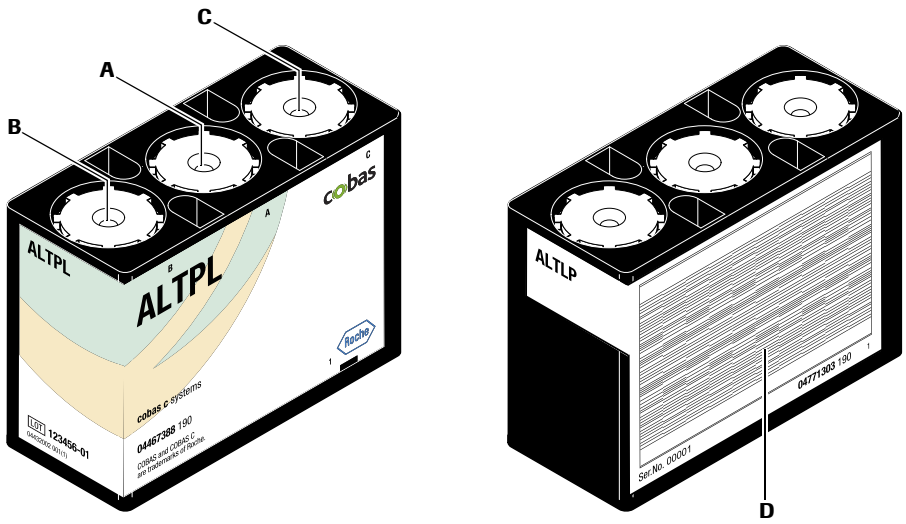
- *Reagents*
- *Diluents*
- *Calibrators and controls*
- *Auxiliary reagents*

Reagents

Each photometric measurement uses reagents.

*Reagent container: **cobas c** pack*

Reagents for **c** 501 module´s photometric units are provided in the **cobas c** packs with two or three containers.



A Bottle position A
B Bottle position B
C Bottle position C
D Barcode

Figure B-57 **cobas c** pack with position designations

*Types of **cobas c** packs*

Two types of **cobas c** packs are available for this module:

- **cobas c** pack: Ready-to-use reagent pack
- **cobas c** pack MULTI: Empty reagent pack for development channel applications

*Configuration of **cobas c** packs*

The **cobas c** packs contain up to three reagent bottles. Pipetting at different times (R1, R2, or R3) is not restricted to any position.

***cobas c** pack MULTI*

For third party reagents, there is the **cobas c** pack MULTI, that is an empty configuration 2 cassette kit (empty but assembled and barcoded cassettes). These kits are used for development channels.

***cobas c** pack registration*

New **cobas c** packs are registered at the cassette preparation station after they have been loaded at the cassette loading port.

The following actions are done at **cobas c** pack registration:

- By reading the cassette barcode, the system checks the availability of the corresponding test application.
- The piercer pierces the reagent bottle caps.

For more information on the cassette preparation station and the cassette loading port, see *Cassette management system* on page A-75.

*Priority of **cobas c** packs*

If there are multiple **cobas c** packs for one application on a **c** 501 module, a **cobas c** pack becomes the active **cobas c** pack in the following order:

1. **cobas c** pack first registered on the system
2. **cobas c** pack with the same lot number as the last active **cobas c** pack
3. **cobas c** pack whose lot expires first

If there are multiple **cobas c** packs with the same lot number, the **cobas c** pack with the oldest registration date becomes the active **cobas c** pack.

A **cobas c** pack with an older registration date that is reloaded on the system becomes the active **cobas c** pack after the system went to standby.

Active **cobas c** packs are also called current **cobas c** packs.

***cobas c** pack volume*

After a **cobas c** pack has been registered, the system counts every pipetting out of this cassette. Thus, the cassette's initial number of available tests is counted down.

When the number of available tests (total number of tests available for an application on one module) is lower than a defined limit, an alarm is issued (yellow or purple alarm, according to configuration under **Utility** > **System** > **Reagent Level Check**).

When the number of available tests becomes zero, a red alarm is issued and the test is masked—unless another **cobas c** pack is available by loading during operation, as a standby **cobas c** pack, or on a second module.

For more information on monitoring the reagent status, see *Reagent Status screen* on page B-130.

*Unloading and reloading **cobas c** packs*

The system counts down each cassette's initial number of available tests with every pipetting out of that cassette. The number of available tests per **cobas c** pack is stored by the system for up to 3000 **cobas c** packs. If you unload a **cobas c** pack and reload it later, the system recognizes the **cobas c** pack and continues the test count at the point where it was unloaded. It is assumed that the **cobas c** pack´s reagent volumes remain unchanged while the **cobas c** pack is not on the analyzer.

For further instructions, see *To unload a reagent cassette* on page B-127.

Carryover prevention

Even though all pipetter probes and reaction cells are washed and rinsed thoroughly after each use, it could be possible that traces of sample or reagent remain on contacted parts (probes or reaction cells) and are carried over at the next pipetting.

Using the special wash function, the system prevents traces of sample liquid or reagent from being carried over and influence the result of a later test.

For more information on programming special washes for **c** 501, see:
Reagent probe wash on page B-298
Cell wash on page B-300
Sample probe wash on page B-302

Diluents

The **c** 501 module´s photometric unit can use for the following diluents, for example:

Product name	Short name[a]	Description	Containers on the analyzer	Code
NaCl 9%	*NaCl*	Diluent for photometric tests	**cobas c** pack	951
Hemolyzing Reagent Gen. 2	*A1CD2*	Diluent for HbA1c whole blood test	**cobas c** pack	952
Water	*H2O*	Deionized water	Water tank	

Table B-12 Diluents for photometric tests

(a) used in this documentation and in the software

The diluent used can be seen on the **Utility** > **Application** > **Analyze** screen.

See *Description of application parameters – Analyze tab* on page B-261.

The parameters for Roche Diagnostics application diluents must be downloaded from **cobas** link. The diluent solution in the **cobas c** pack can be a concentrated solution (for example, a **cobas c** pack with NaCl 9%. The 9% solution is diluted with water to a concentration of 0.9% by the analyzer).

To monitor the remaining amount of diluent, set a reagent warning level.

Calibrators and controls

The **c** 501 module´s photometric unit needs calibrators and controls.

Calibrators

For photometric applications, multi-analyte calibrators (for example, CFAS) and special calibrators (for example, CFAS Hba1c) are available. The same multi-analyte calibrator is used for a large number of applications whereas a special calibrator covers only a few or only one application.

Multi-analyte calibrators for **c** 501 applications are CFAS (without diluent), CFAS Proteins, or CFAS Proteins Urine/CSF.

For information about calibrators for specific applications, refer to the corresponding instructions for use.

Controls

For photometric applications, multi-analyte controls (for example, PreciControl ClinChem Multi 1 and Multi 2) and special controls (for example, PreciControl HbA1c norm) are available. The same multi-analyte control is used for a large number of applications, whereas a special control covers only a few or only one application.

Multi-analyte quality controls are PNU and PPU.

For information about quality controls for specific applications, refer to the corresponding instructions for use.

Auxiliary reagents

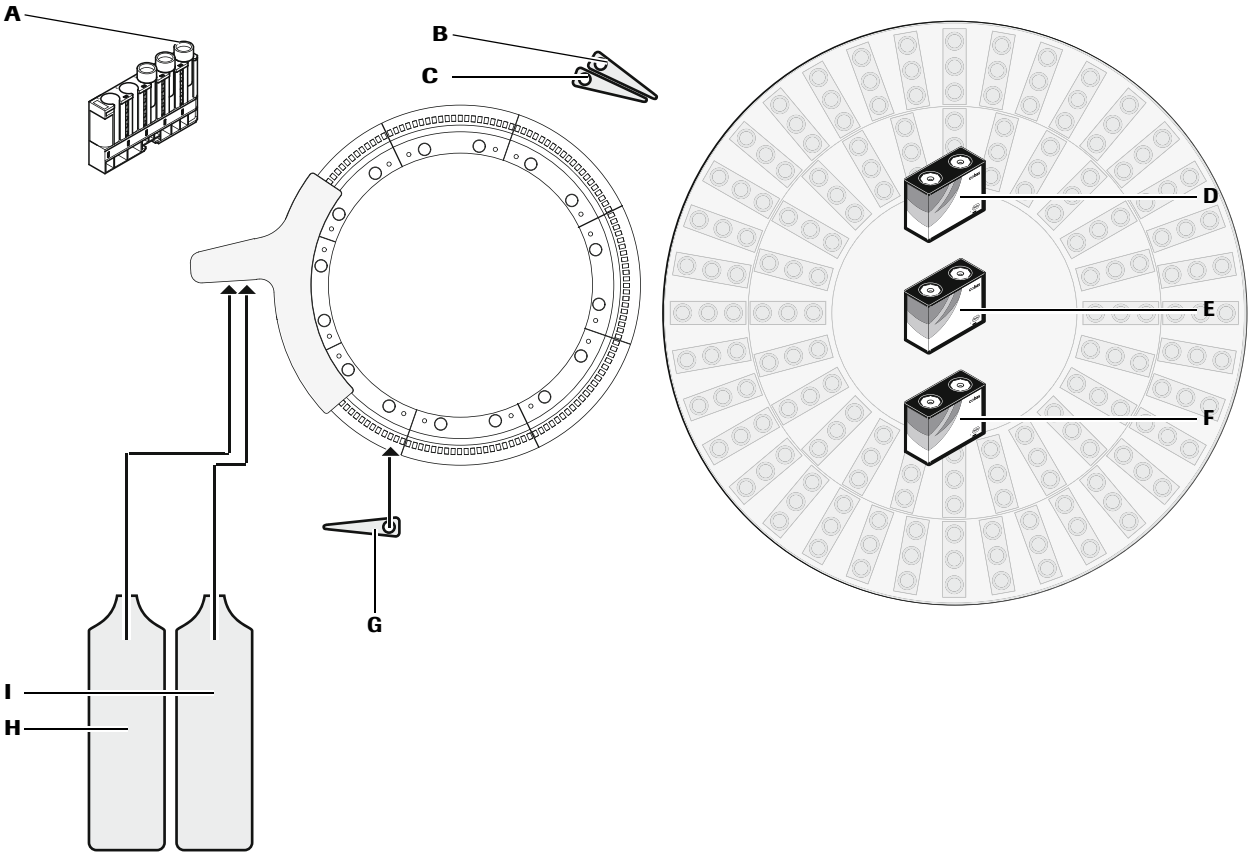
The **c** 501 module´s photometric unit uses the following auxiliary reagents:

Product name	Short name[(a)]	Description	Containers on the analyzer	Location	Figure B-58
Cell Wash Solution I / NaOH-D	CellCln 1	NaOH-D, used for rinsing and cleaning reaction cells	1 large bottle	Behind the left front door	**H**
Cell wash Solution II / Acid Wash	CellCln 2	Acid wash, test specific, used for rinsing and cleaning reaction cells	1 large bottle		**I**
Sample Cleaner 1	SmpCln 1	Sample probe wash solution 1, NaOH	1 bottle of 70 mL	Reaction disk area	**B**
Sample Cleaner 2	SmpCln 2	Sample probe wash solution 2, acid wash	1 bottle of 70 mL		**C**
EcoTergent	BathDet	Surfactant for incubator bath to prevent algae proliferation and foaming	1 bottle of 70 mL	Reaction disk area	**G**
Detergent 1	NaOH-D	For reagent probe wash and cell wash (Maintenance item (7) Wash Reaction Parts)	1 **cobas c** pack ACN 947	Reagent rotor	**D**
Detergent 2	SMS	For reagent probe wash and cell wash	1 **cobas c** pack ACN 948		**E**
Detergent 3	SCCS	Solution, used for reaction cell carryover prevention in long HbA1c batches	1 **cobas c** pack ACN 949		**F**
Sample Cleaner 1	SmpCln 1	Washing the sample probe	Sample tube or cup on green wash rack	Rack Pos. 1	**A**

Table B-13 Auxiliary reagents for photometric tests

(a) used in this documentation and in the software

Location The figure below gives an overview of the auxiliary reagents used by the **c** 501 module´s photometric unit and their location.



A	Sample Cleaner 1 (green wash rack, 1)	**D**	NaOH-D (**cobas c** pack)	**G**	EcoTergent
B	Sample Cleaner 1	**E**	SMS (**cobas c** pack)	**H**	Cell Wash Solution I / NaOH-D
C	Sample Cleaner 2	**F**	SCCS (**cobas c** pack)	**I**	Cell wash Solution II / Acid Wash

Figure B-58 Location of auxiliary reagents for photometric tests

To locate these auxiliary reagents on the analyzer, see:
Behind the front doors on page A-86
Figure B-154 on page B-303

Auxiliary reagent volume

The remaining volumes are displayed on the **Reagent** > **Status** screen. Whenever a reagent bottle is replaced, the operator has to reset the initial volume. Reagent registration is not performed automatically when a new bottle is loaded.

The table below describes the reagent volume control and reset action for the auxiliary reagents of the **c** 501 module´s photometric unit.

Auxiliary	Volume control	Reset
Cell Wash Solution I / NaOH-D Cell wash Solution II / Acid Wash	countdown[(a)]	User action[(b)] (in standby only)
EcoTergent	LLD by ISE probe	User action[(b)]
Sample Cleaner 1 Sample Cleaner 2	LLD by sample probe	User action[(b)]
NaOH-D SMS SCCS	countdown[(a)]	By the instrument during **cobas c** pack registration

Table B-14 Auxiliary reagents: Remaining volume control

(a) The remaining volumes of the auxiliary reagent are monitored by countdown, starting from a given initial volume.

(b) **Reagent** > **Status** > **Reagent Volume Reset**

For more information on monitoring the reagent status, see:
Reagent Status screen on page B-130
To reset initial volumes of auxiliary reagents on page B-131
cobas c pack registration on page B-109

Reagent concept – e 601

This section provides information about all reagents used on the **e** 601 module including auxiliary reagents, diluents, calibrators, and controls. It also describes the reagent containers used on this module.

Reagents for immunoassay

This section describes all reagents necessary to run immunoassays on the **e** 601.

Overview of reagents for immunoassays

The **e** 601 module requires the following reagents:

- Assay-specific reagents
- *Pretreatments*
- *Diluents*
- *Calibrators and controls*
- *Auxiliary reagents*

*Color code of **cobas e** packs*

The following table shows the color code of the **cobas e** packs that are used for reagents, pretreatments, and diluents.

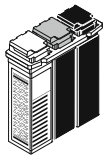
	Reagent		Pretreatment		Diluent	
	Bottle	**Cap**	**Bottle**	**Cap**	**Bottle**	**Cap**
1st container	transparent	transparent	black	black	black	white
2nd container	black	gray	transparent	white	(black)	(white)
3rd container	black	black				
						

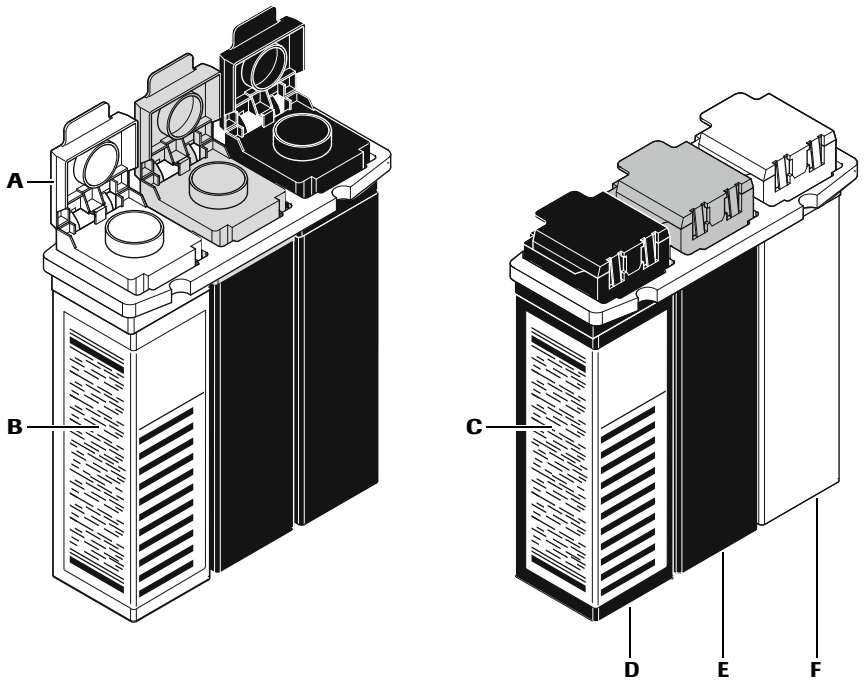
Table B-15 Color code of the **cobas e** packs

Reagents

Each measurement uses reagents.

*Reagent container: **cobas e** pack*

Reagents for **e** 601 module are provided in **cobas e** packs with three containers.



A Cap of the reagent container
B Barcode label used for Elecsys systems
C Barcode label used for **cobas** 6000 analyzer series
D Reagent 2 (R2)
E Reagent 1 (R1)
F Microbeads

Figure B-59 **cobas e** pack for reagents

*Types of **cobas e** packs*

Depending on the assay two types of reagent kits are available:

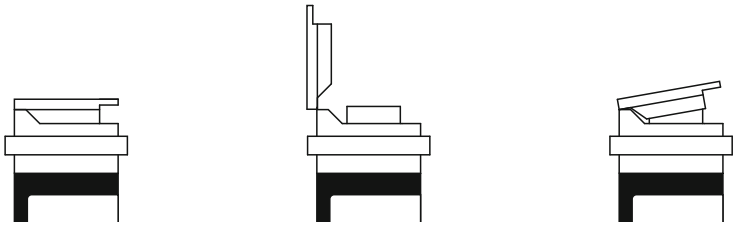
- **cobas e** pack
- **cobas e** pack plus **cobas e** pack for pretreatment

For more information about **cobas e** pack for pretreatments, see *Pretreatments and the PT link function* on page B-118.

*Caps of **cobas e** pack*

The reagent containers of the **cobas e** packs are equipped with caps (**A**). The caps prevent evaporation of the reagents.

The **e** 601 module is equipped with an open/close mechanism for the caps of the **cobas e** packs. The mechanism is able to open and close the caps automatically if the caps are in the so-called *soft-close position*: The caps are almost closed, but not tightly closed.



A Cap: Closed **B** Cap: Open **C** Cap: Soft-close position

Figure B-60 Caps of **cobas e** pack: Soft-close position

*Configuration of **cobas e** packs*

A **cobas e** pack consists of three separately capped containers.

1st container	Microbeads
2nd container	Reagent 1 (R1)
3rd container	Reagent 2 (R2)

An individual **cobas e** pack is available for each **e** 601 application.

For the color code of the **cobas e** packs, see *Color code of cobas e packs* on page B-114.

***cobas e** pack registration*

New **cobas e** packs are registered by scanning the barcode.

Barcode

The **cobas e** packs are equipped with a barcode label. The analyzer scans this barcode label each time the operator closes the reagent cover. The system scans all **cobas e** pack barcodes at once.

Unreadable barcode

cobas e packs must be inserted into the reagent disk with their barcode label facing the center of the reagent disk.

If a **cobas e** pack's barcode is unreadable, it can be registered manually by entering the 15-digit number on barcode label. This number is only accepted if one barcode of the same test and lot number was already successfully scanned and registered on the system.

For manual registration of **cobas e** packs, see *Manual reagent registration* on page B-126.

*Priority of **cobas e** packs*

If there are multiple **cobas e** packs for one application on an **e** 601 module, a **cobas e** pack becomes the active **cobas e** pack in the following order:

1. **cobas e** pack first registered on the system
2. **cobas e** pack with the same lot number as the last active **cobas e** pack

 If there are multiple **cobas e** packs with the same lot number as the last active **cobas e** pack:

 a) The **cobas e** pack with the oldest registration date
 b) The **cobas e** pack with the least remaining volume
 c) The **cobas e** pack on the lowest position number on the reagent disk
3. **cobas e** pack with the lot number that expires first

Active **cobas e** packs are also called current **cobas e** packs.

***cobas e** pack volume*

The system counts down the initial number of available tests.

When the number of available tests (total number of tests available for an application on one module) is lower than a defined limit, an alarm is issued (yellow or purple alarm, according to configuration under **Utility** > **System** > **Reagent Level Check**).

When the number of available tests becomes zero, a red alarm is issued and the test is masked—unless another **cobas e** pack is available as a standby **cobas e** pack or on a second module.

For more information on monitoring the reagent status, see *Reagent Status screen* on page B-130.

Carryover prevention

Heterogeneous immunoassays are very sensitive tests. Some combinations of these assays are especially sensitive against carryover within the **e** 601 module. To prevent such carryover, special wash programs are pre-programmed on **Utility** > **Special Wash > Immune**.

For more information on programming special washes for **e** 601, see *Reagent probe wash* on page B-304.

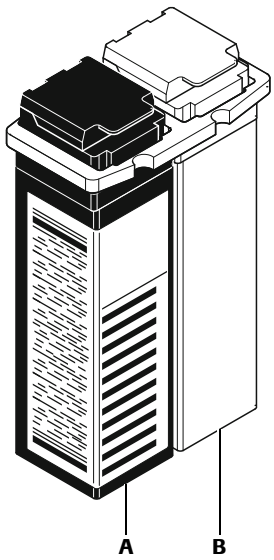
Pretreatments and the PT link function

Some analytes are not detectable in the native sample. Therefore, some immunoassays use a pretreatment procedure to prepare the sample for measurement.

For information about pretreatments, refer to the instructions for use of the respective application.

*Pretreatment container: **cobas e** pack*

Pretreatments are provided in **cobas e** packs with one or two containers.



A Pretreatment 2
B Pretreatment 1

Figure B-61 Pretreatments **cobas e** pack

For more information about the **cobas e** pack for pretreatment, see *Reagents* on page B-115.

*Configuration of pretreatment **cobas e** packs*

A pretreatment **cobas e** pack consists of one or two capped reagent containers.

1st container	Pretreatment bottle 1 (PT1)
2nd container	Pretreatment bottle 2 (PT2)

*Linked with reagent **cobas e** pack*

After registration, a pretreatment **cobas e** pack always forms a pair with a reagent **cobas e** pack of the same test and the same lot. This function is called PT link. The linkage is required from the stability point of view.

- Once a reagent **cobas e** pack and a pretreatment **cobas e** pack are linked together, none of them can be linked to another **cobas e** pack.
- The lower number of remaining tests in one of the linked **cobas e** packs determines the number of available tests. A liquid level detection is performed during aspiration of pretreatment.
- If one **cobas e** pack in the pair becomes empty, the remaining number of tests for the linked **cobas e** pack is set to 0. Both **cobas e** packs cannot be used anymore.

Link statuses

Both **cobas e** packs can have one of the following link statuses:

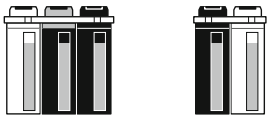
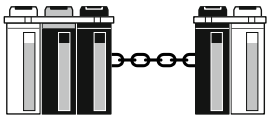
Link Status		Explanation
Free		The **cobas e** pack is not yet linked to any other **cobas e** pack and has not been used before. Free **cobas e** packs are not available for measurement.
Linked		The **cobas e** packs are linked together. If both **cobas e** packs are on board, the reagent is available for use. If one **cobas e** pack becomes empty, both reagents are not available for measurement.

Table B-16 Explanation of the link statuses

If a **cobas e** pack is linked, it can never receive the status **Free** again.

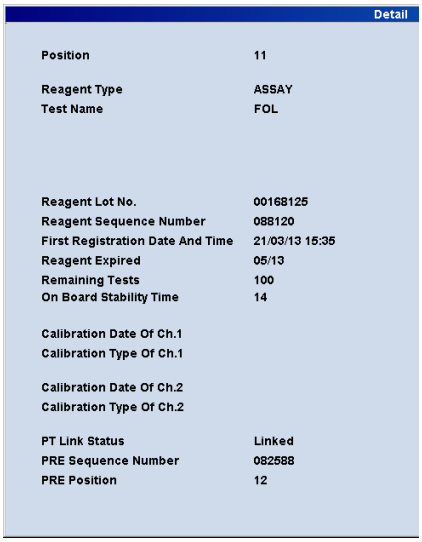
cobas e packs already used before software update

After updating to the current software version with the PT link function, some **cobas e** packs may still have the link status **Free** even though they have been used. The PT link function will be used for the next fresh **cobas e** packs.

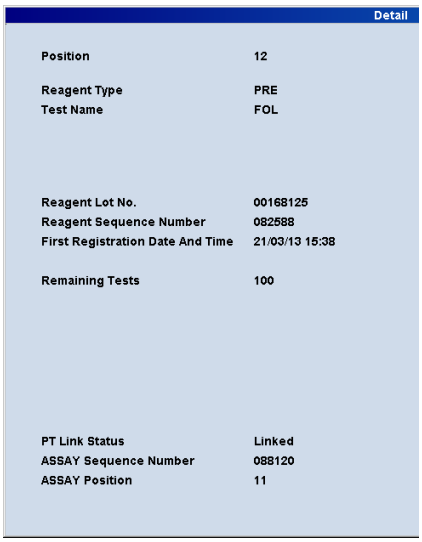
Linking rules and timing

The instrument registers **cobas e** packs automatically when the reagent disk cover is closed. If the instrument recognizes a reagent **cobas e** pack with the link status **Free**, the instrument tries to find an available pretreatment **cobas e** pack. This pretreatment **cobas e** pack must fulfill the following conditions:

- The lot number and the **Code** (**Reagent** > **Setting** screen list) are identical with those of the reagent **cobas e** pack.
- The pretreatment **cobas e** pack has the status **Free**.



Detail window for the reagent **cobas e** pack



Detail window for the pretreatment **cobas e** pack

Figure B-62 **Detail** window

Diluents

Dilution of samples is necessary when the analyte concentrations exceed the measuring range of the respective immunological test method. In addition, general dilution of samples is specified for some immunological tests.

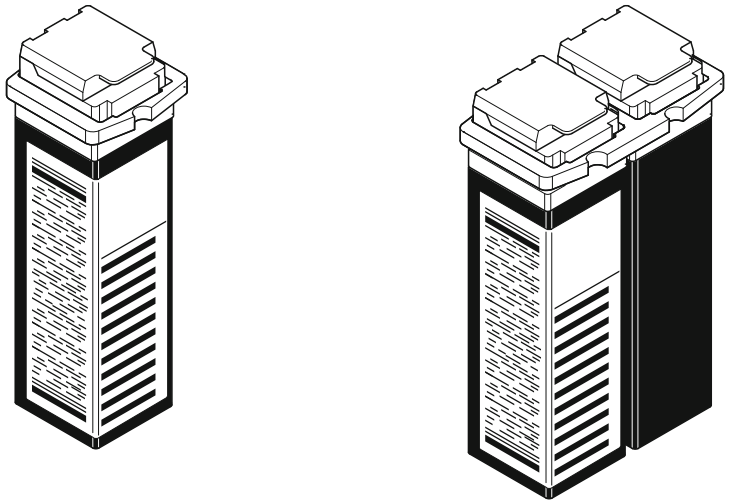
Examples for diluents are:

- Diluent Universal
- Diluent MultiAssay

👁 For information on required diluents and recommended dilution factors, refer to the instructions for use of the respective application.

Diluent container: ***cobas e*** *pack*

Diluents for **e** 601 modules are available in the **cobas e** packs.



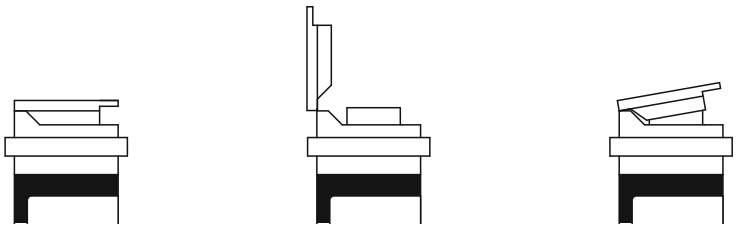
cobas e pack for diluent with one container **cobas e** pack for diluent with two containers

Figure B-63 **cobas e** pack for diluent

Caps of ***cobas e*** *pack for diluent*

The diluent containers of the **cobas e** packs are equipped with caps (**A**). The caps prevent evaporation of the diluent.

The **e** 601 modules are capable of opening and closing these caps automatically if the caps are in the so-called *soft-close* position: The caps are almost closed, but not tightly closed. This ensures the caps can be opened by the mechanism in all cases.



A Cap: Closed **B** Cap: Open **C** Cap: Soft-close position

Figure B-64 Caps of **cobas e** pack: Soft-close position

Configuration of ***cobas e*** *packs for diluent*

The **cobas e** packs for diluent consist of one or two separately capped diluent containers.

1st container	Diluent
(2nd container)	(Diluent)

*One- or two-container **cobas e** pack for diluent*

Usually the **cobas e** packs for diluent consist of one container. In addition, some diluents are also supplied in **cobas e** packs for diluent with two containers.

If a diluent is provided as **cobas e** packs for diluent with one or two containers, the user must decide which **cobas e** pack for diluent to load on the system. This depends on the following aspects:

- The consumption of this diluent of the corresponding **e** 601 module
- The on-board stability of the **cobas e** pack for this diluent

The **cobas e** pack for diluent should be empty before its on-board stability expires.

*Priority of **cobas e** packs for diluent*

If there are multiple **cobas e** packs for one diluent on an **e** 601 module, a **cobas e** pack for diluent becomes the active **cobas e** pack for diluent in the following order:

1. **cobas e** pack for diluent first registered on the system
2. **cobas e** pack for diluent with the same lot number as the last active **cobas e** pack for diluent

 If there are multiple **cobas e** packs for diluent with the same lot number as the last active **cobas e** pack for diluent:

 a) The **cobas e** pack for diluent with the oldest registration date
 b) The **cobas e** pack for diluent with the least remaining volume
 c) The **cobas e** pack for diluent on the lowest position number on the reagent disk
3. **cobas e** pack for diluent with the lot number that expires first

Active **cobas e** packs for diluent are also called current **cobas e** packs for diluent.

Application specific

If a test uses a diluent, the required diluent is specified in the application. An automatic dilution is only possible with the specified diluent.

One diluent can be specified for multiple applications.

For the specified diluent, refer to the instructions for use of the **cobas e** pack.

Reagent Load/Unload list

If you load a **cobas e** pack for a new application that requires a diluent, this diluent is not listed on the **Reagent Load/Unload List**.

Define the yellow and the purple alarm levels for all diluents to ensure that there are always sufficient diluents on the **e** 601 module.

For defining the yellow and purple alarm level, see *Reagent Level Check window* on page E-388.

Missing diluent

If a test requires dilution and the appropriate diluent is not available, the system behaves as follows:

- **Workplace** > **Test Selection** screen: Test is masked
- **System Overview** screen: Module is displayed in red

Test configuration

On **cobas** 6000 analyzer series with two **e** 601 modules, install the tests that required the same diluent on the same **e** 601 module. This saves space on the reagent disk of the **e** 601 module.

Calibrators and controls

The **e** 601 module´s immunological unit needs calibrators and controls.

Calibrators Immunological applications use test-specific calibrator sets called CalSets. A calset comprises two levels: cal1 and cal2.

For information about calibrators for specific applications, refer to the corresponding instructions for use.

Controls For immunological applications multi-analyte controls and specific controls are available. The same multi-analyte control is used for a large number of applications, whereas a specific control covers only one application.

For information about quality controls for specific applications, refer to the corresponding instructions for use.

Auxiliary reagents

The **e** 601 uses the following auxiliary reagents:

Product name	Short name[a]	Description	Containers on the analyzer	Location
ProCell M	ProCell	Conditioning of the electrodes Transport of the assay reaction mixture Bound-free separation in measuring cell Signal generation	2 bottles of 2 L	Behind the front doors
CleanCell M	CleanCell	Cleaning of tubing system and measuring cell after every measurement Conditioning of the electrodes	2 bottles of 2 L	
PreClean M	PreClean	To remove potentially interfering substances in the prewash procedure Required only for certain assays. Its use is indicated under *materials required (but not provided)* in the respective assay reagent instructions for use	2 bottles of 600 mL	
ProbeWash M	ProbeWash	Cleaning the reagent probe during special wash steps and finalization	2 bottles of 70 mL	Near the reagent probe
SysClean	SysClean	Sodium hypochlorite solution used for intensive cleaning of the measuring cells (maintenance procedure *liquid flow path cleaning*)		Not on the analyzer

Table B-17 Auxiliary reagents for immunological tests

(a) used in this documentation

Auxiliary reagent volume

The remaining volumes are displayed on the **Reagent** > **Status** screen.

The table below describes the reagent volume control and reset action for the auxiliary reagents of the **e** 601 module.

Auxiliary	Volume control	Reset
ProCell	countdown[a]	User action[b]
CleanCell	countdown[a]	User action[b]
PreClean	countdown[a]	User action[b]
ProbeWash	LLD by reagent probe	LLD by reagent probe[c]

Table B-18 Auxiliary reagents: Remaining volume control

(a) The remaining volumes of the auxiliary reagent are monitored by countdown, starting from a given initial volume.

(b) Pressing the flashing button.

(c) After executing the inventory update.

For more information on monitoring the reagent status, see:
Reagent Status screen on page B-130
To replace empty ProbeWash on page B-135

Operator-related reagent management

The following sections describe tasks and data that can be accessed by the screens under the **Reagent** menu. The **Reagent** menu contains two screens: The **Reagent** > **Setting** screen and the **Reagent** > **Status** screen. In addition, the **Reagent Overview** button on the **System Overview** screen as well as windows accessed via this button are explained.

However, this chapter does not cover all possible commands. For a complete description of all fields of the software's user interface, refer to the *Online Help*.

Reagent > Setting screen

The **Reagent** > **Setting** screen provides detailed information about each test reagent and position for each installed module. The compiled data include reagent codes, lot numbers, expiration dates (shelf life) as well as on board stability of reagents (in days). Tasks that can be performed from this screen are:

- Priming reagents (ISE and **e** 601)
- Unloading **cobas c** packs (**c** 501)
- Manually registering **cobas e** packs (**e** 601)
- Open channel (**c** 501)
- Loading a **cobas c** pack MULTI for a Development Channel application (**Open Channel** – **c** 501)

Reagent > Status screen

The **Reagent** > **Status** screen provides all important data about test reagents to monitor the reagent status on the analyzer. The data are sorted according to the names of the applications and displayed either for all modules or for one specified module. Moreover, there is an additional list, which provides information about auxiliary reagents. Tasks that can be performed from this screen are:

- Resetting the remaining volume control for auxiliary reagents (**c** 501)
- Entering ProCell lot numbers (**e** 601)

For more information, see:
Reagent Setting screen on page B-125
Reagent Status screen on page B-130

System Overview screen > Reagent Overview button

By changing its color, the **Reagent Overview** button indicates potentially insufficient amounts of reagent on the module currently selected in the **Module Overview** area. Choose this button to view details about the status of loaded reagents.

See *Reagent Overview button* on page B-141.

Reagent Setting screen

To display this screen, choose **Reagent** > **Setting**.

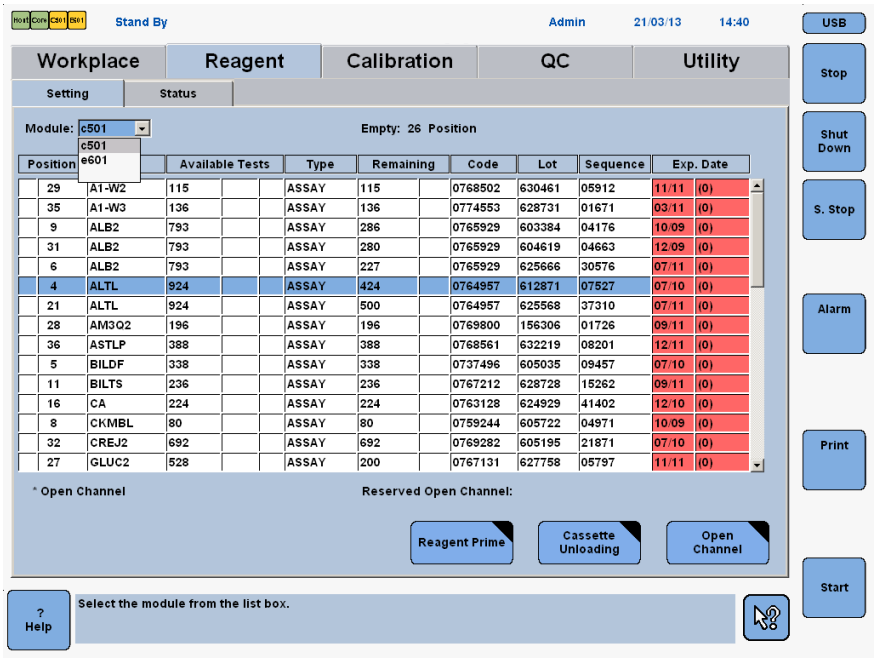


Figure B-65 Reagent Setting screen

This screen comprises a **Module** box (on the top left), a large test list, and several buttons. The buttons available as well as the view of the test list change according to the module selected from the **Module** box.

For more information about the different fields and buttons on this screen, refer to the *Online Help* of the particular field or button.

Manual Registration (e 601) Use this button to manually register a **cobas e** pack; that is, to manually enter a **cobas e** pack barcode number.

For more information, see *Manual reagent registration* on page B-126.

Reagent Prime Use this button to prime reagents either of the **e** 601 (ProCell, CleanCell, PreClean) or of the ISE unit (ISE IS, ISE Ref.).

For more information, see:
Reagent Preparing button on page B-44
To perform a Reagent Prime on page B-48
Reagents on page B-106
Auxiliary reagents on page B-122

Cassette Unloading (c 501) Use this button to unload a reagent cassette either to the cassette loading port or to the cassette disposal.

For more information, see *Loading and unloading of reagent cassettes (c 501)* on page B-127.

Manual reagent registration

⚠ CAUTION

Incorrect results due to cobas e pack barcode read error

There is a risk of **cobas e** pack mismatch during manual **cobas e** pack registration. If a **cobas e** packs is not placed in the proper position, incorrect measurement results may occur.

- After manual registration, thoroughly check the reagent information.
- If a new barcode read error occurs after manual registration of a **cobas e** pack, check if the **cobas e** pack is the correct position.

A manual reagent registration for the **c** 501 is not available. The **c** 501 automatically registers all new **cobas c** packs, if the corresponding application is installed. The initial reagent volume is counted down with each pipetting.

The **e** 601 automatically registers all new **cobas e** packs. In case the automatic registration fails (if system is unable to read the barcode), you can manually register a **cobas e** pack from the **Manual Registration** (**e** 601) window.

► To manually register a cobas e pack

1. Select an **e** 601 from the **Module** box on the **Reagent** > **Setting** screen.
2. Select the position of the **cobas e** pack for which the automatic registration failed.

 The **cobas e** packs for which the automatic registration failed is indicated by ---- in the **Test** column. The **Manual Registration** button becomes active if you select this position.
3. Choose **Manual Registration** to open the **Manual Registration** (**e** 601) window.
4. Type the barcode of the **cobas e** pack to be registered (15 digit number).
5. Choose **OK**.

■

It is only possible to manually register a **cobas e** pack if at least one **cobas e** pack of the same lot was scanned in before.

Loading and unloading of reagent cassettes (c 501)

Loading reagent cassettes

Load **cobas c** packs at the loading port behind the arched flap at the front of the **c** 501 module. When loading, make sure the cassette's barcode label is facing to the right. Reagent registration is performed automatically when a new reagent cassette is loaded.

For more details, see *Replacing cobas c packs* on page B-49.

Unloading reagent cassettes

The **c** 501 module automatically unloads empty reagent cassettes to the cassette disposal. If you need to manually unload a reagent cassette, you have the choice either to send it to the cassette loading port (option **Unload**) or to send it to the cassette disposal (option **Dump**). In case you intend to reload the reagent cassette, choose **Unload**.

If you use the option **Dump** for unloading a cassette, the cassette cannot be reloaded.

► To unload a reagent cassette

1. Put the module in standby.
2. Select a **c** 501module from the **Module** box on **Reagent** > **Setting**.
3. Select the position of the reagent cassette that is to be unloaded.
4. Choose **Cassette Unloading** to open the **Cassette Unloading** window.
5. Choose either **Unload** (to send the cassette to the cassette loading port) or **Dump**.
6. Choose **Execute**.

■

Reagent reloading (e 601)

Reagent reloading is a function that automatically starts a reagent reloading process on a particular module. It is separately selectable for each application on that module.

Reloading process

If selected, the reloading process starts when the number of remaining tests for the respective application becomes zero.

For more information, see *To assign a test to an e 601 module* on page B-289.

The reloading process comprises the following items:

1. The following caution-level alarm (yellow) is issued: **Reagent reloading**.

 The alarm code is within the range of 381-xxxx through 386-xxxx, where the subcode xxxx indicates the affected application: xxxx corresponds to the application code number (for example 1052 corresponds to CA15-3 with ACN 52).

2. The module automatically stops pipetting. The racks in the siding line are transported to their destination (other modules, rack rotor, or rack unloader). Other racks which have already passed the barcode reader are no longer transported into this particular module. All samples which are in process are measured.
3. After the results are available, the module turns to stand by. Reagents can be reloaded.

 Stand by and reload possibility is indicated both in the status line and on the **System Overview** screen by the module being displayed in pink.

4. After closing the reagent cover, reagent registration is automatically performed.

 After that liquid level detection and initial beat mixing is performed (Preparation).

5. Finally, the module returns to operation.

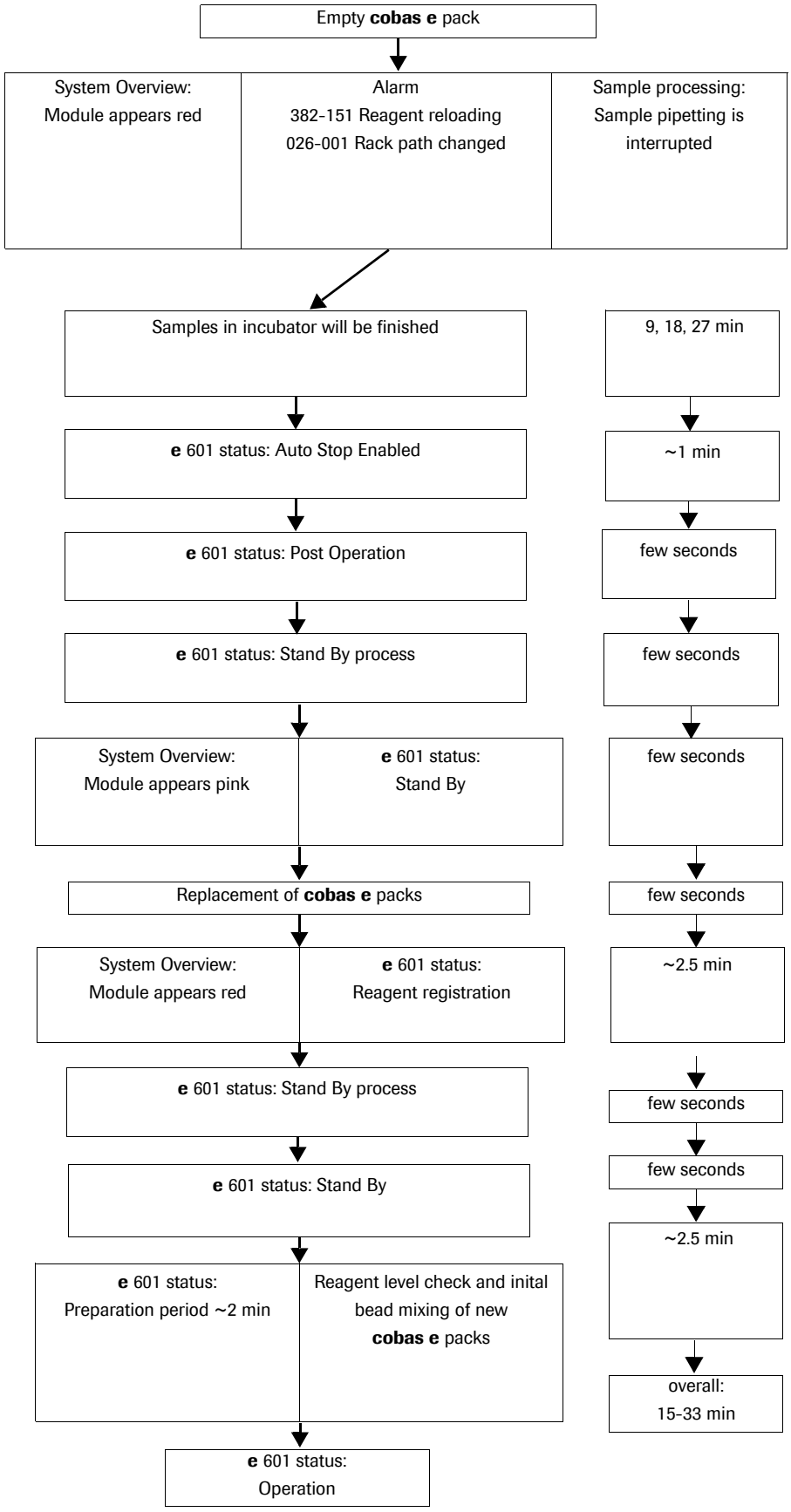


Figure B-66 Reagent reloading process (**e** 601)

Reagent Status screen

To display this screen, choose **Reagent** > **Status**.

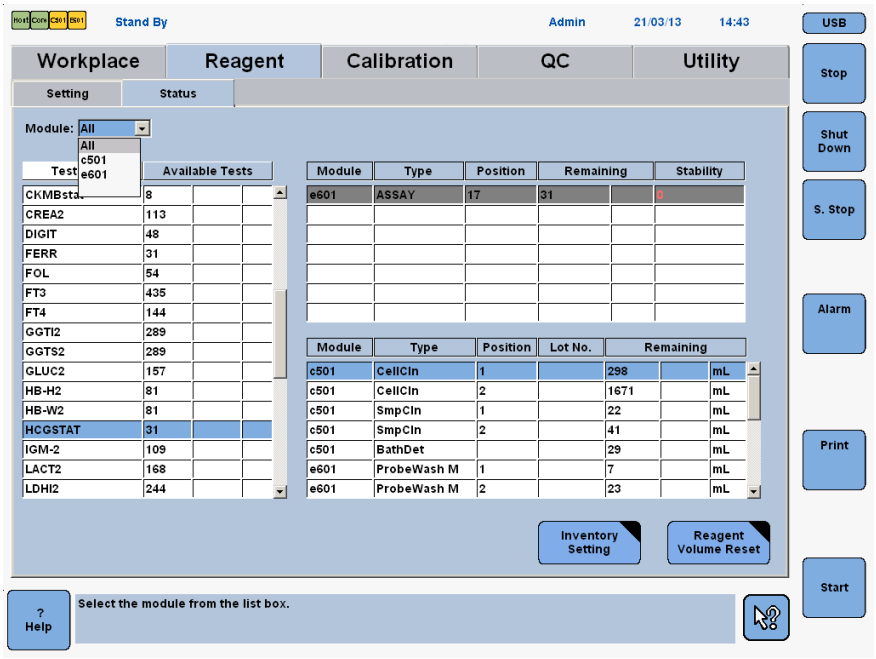


Figure B-67 Reagent Status screen

The **Reagent** > **Status** screen displays reagent data for all tests on the analyzer. The screen comprises a **Module** box (on the top left), a test list, a detailed reagent list (on the top right), and auxiliary reagent list (on the bottom right).

Replacing auxiliary reagents (c 501)

When replacing auxiliary reagent bottles (such as cell detergent or sample probe detergent bottles), you have to manually reset the software's reagent volume count.

Follow the procedures below to replace auxiliary reagent bottles and reset their volume count:

► To replace a cell detergent bottle

1 Put the system in standby.

2 Open the front door of the module.

3 Replace required reagent bottle and clean the aspiration filter.

👁 See *Cleaning the detergent aspiration filters* on page C-94.

CAUTION! Incorrect results due to incorrect insertion of aspiration tube. Insert the aspiration tube so that the end of the tube touches the bottom of the bottle. Do not bend the aspiration tube.

4 Reset the volume count under **Reagent** > **Status** > **Reagent Volume Reset**.

👁 See *Resetting initial volumes of auxiliary reagents (c 501)*.

■

► To replace Sample Cleaner 1 and 2 or EcoTergent

1 Put the analyzer in stand by.

2 Unlock and open the top cover of the module.

Improper aspiration of detergent due to foam or air bubbles

- Do not shake or drop the detergent bottles before placing them on the analyzer.

3 Replace required reagent bottle

4 Reset the volume count under **Reagent** > **Status** > **Reagent Volume Reset**.

👁 See *Resetting initial volumes of auxiliary reagents (c 501)*.

■

*Resetting initial volumes of auxiliary reagents (**c** 501)*

The remaining volumes of cell detergents and other auxiliary reagents are monitored by counting down from the initial volume of a full reagent bottle. When you place a new reagent bottle, you always have to manually reset this volume countdown.

Only reset the reagent volume count in the software after a new reagent bottle has been placed.

► To reset initial volumes of auxiliary reagents

1 Select a **c** 501 from the **Module** box on the **Reagent** > **Status** screen.

2 Select the current reagent from the auxiliary reagents list (on the bottom right) whose volume needs to be reset.

3 Choose **Reagent Volume Reset**.

4 Choose **OK** to confirm the reset.

■

Replacing auxiliary reagents (e 601)

Illuminated green push buttons indicate the status of the ProCell/CleanCell and PreClean bottles. The green buttons indicate when it is safe for you to replace a reagent bottle:

Off	The bottle is in use, do not replace it when the module is in operation or other mode but standby.
On	This is a standby bottle, do not replace it when the module is in operation or other mode but standby.
Flashing	The bottle is empty, it is safe to replace it. (When air bubbles are detected, this button also flashes.)

For more information, see:
Auxiliary reagents and cleaning solutions on page A-106
Reagents for immunoassay on page B-114

Replacing empty auxiliary reagents

If an auxiliary reagent bottle is empty, the corresponding button is flashing. Replace this auxiliary reagent bottle.

Replacing empty ProCell and CleanCell

Two bottles of ProCell and two bottles of CleanCell are located behind the front door of the **e** 601 module.

For more information, see *ProCell and CleanCell bottles* on page A-107.

► To replace empty ProCell (PC)/CleanCell (CC)

1 Open the middle door of the **e** 601.

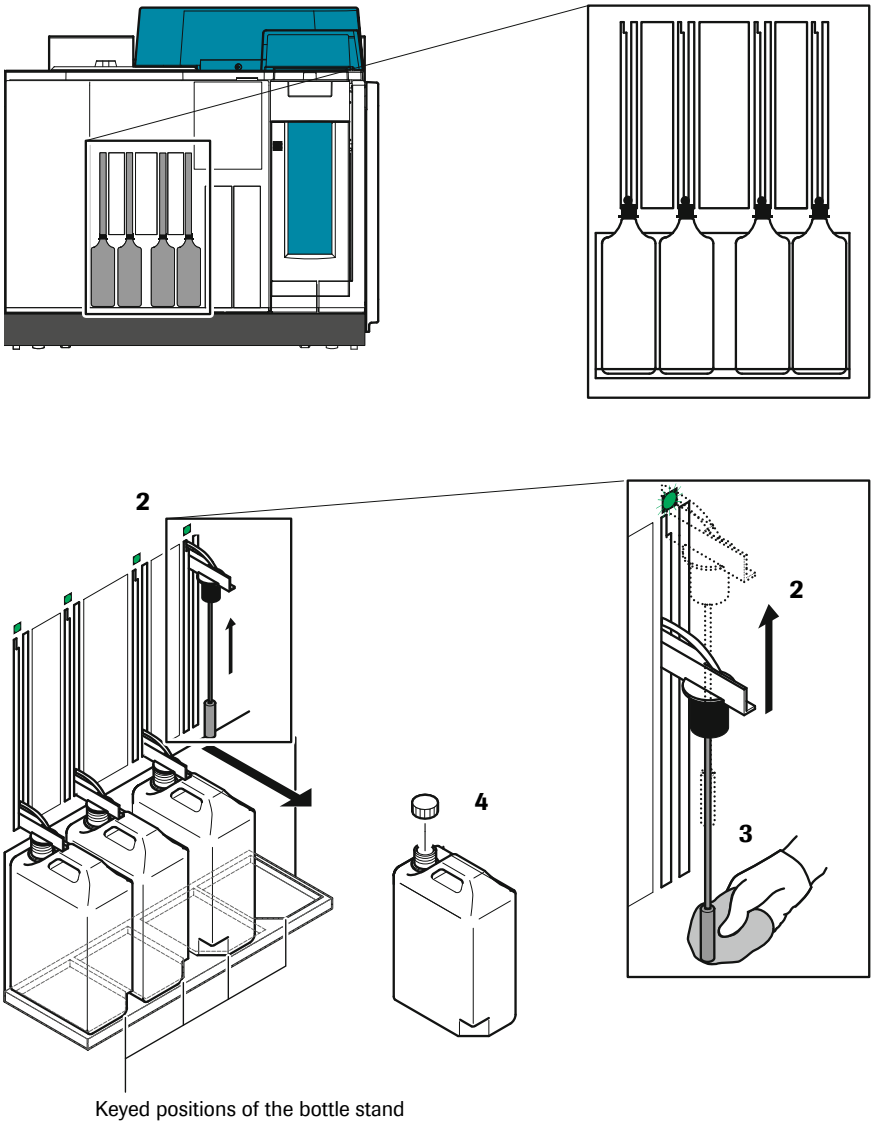


Figure B-68 Replacing ProCell/CleanCell bottles

Only replace a bottle if the green button is flashing.

CAUTION! False results due to loose ProCell/CleanCell aspiration tube filters. Make sure the aspiration tube is pulled up and hooked on to its notch, before removing the bottle. After replacing the bottle, unhook the aspiration tube and lower it slowly into the bottle, do not let it drop into the bottle.

2 Pull the aspiration tube up and to the left to secure them on their respective notches.

3 Absorb the liquid with lint-free gauze squares.

CAUTION! False results due to ProCell/CleanCell bottle misplacement. ProCell and CleanCell bottles are different in shape to fit the keyed position of the bottle stand. Ensure the bottle stand is present before placing the ProCell and CleanCell bottles.

4 Remove the empty bottle, indicated by the flashing green button, and replace it with a full bottle ensuring that it is firmly in place.

5 Lower the aspiration tube into the new bottle.

6 Press the flashing green button corresponding to the position in which the new bottle has been placed to inform the system that a new bottle was loaded. The button will be illuminated indicating that this is a standby bottle.

Only press the green button after you have replaced a bottle. Do not press the green button under any other circumstances.

7 Close the middle door of the **e** 601.

8 If a ProCell bottle with a new lot number was loaded, enter the lot number on the **Reagent** > **Status** > **Inventory Setting**.

- Choose **Inventory Setting** to open the **Inventory Setting** window.
- Type the new lot number into the box for ProCell Position 1 or 2, respectively.
- Choose **Execute**.

■

Replacing empty PreClean

Two bottles of PreClean are located in the inner side of the front door of the module.

For more information, see *PreClean bottles* on page A-107.

► To replace empty PreClean

1 Open the middle door at the front of the required module.

CAUTION! If you do not properly load the PreClean bottles the volume available for pipetting may be less than expected by the system and therefore cause deterioration in measurement accuracy.

2 Remove the empty bottle, indicated by the flashing green button. Replace it with a full bottle ensuring that it is firmly in place and that the needle has pierced the bottle. Loosen the cap to allow air into the bottle.

3 Press the flashing green button corresponding to the position in which the new bottle has been placed to inform the system that a new bottle has been loaded. The button will be illuminated indicating that this is a standby bottle.

Only press the green button after you have replaced a bottle. Do not press the green button under any other circumstances.

4 Close the middle door of the **e** 601.

■

Replacing empty ProbeWash

Two bottles of ProbeWash are located on the analytical module near the reagent probe.

See *ProbeWash station* on page A-98.

The 2 ProbeWash bottles can simply be replaced when necessary, as the reagent probe is equipped with a liquid level detector (LLD) which senses the remaining volume.

► To replace empty ProbeWash

1. Put the system in standby or mask the affected module.
2. Remove the empty ProbeWash bottle from position 1.
3. Move the ProbeWash bottle from position 2 to position 1.
4. Remove the cap from the new ProbeWash bottle.
5. Place the new ProbeWash bottle in position 2.
6. If the module is masked, unmask the module.
7. The level is checked and the inventory is automatically updated.

■

Replacing auxiliary reagents when not empty (green light is not flashing)

Under some conditions an auxiliary reagent has to be replaced while the green button is not flashing, before the bottle is empty. For example if:

- The expiration date on the label of the auxiliary reagent bottle is exceeded.
- The on-board stability specified in the instructions for use is expired.

Replacing ProCell and CleanCell when not empty

Two bottles of ProCell and two bottles of CleanCell are located behind the front door of the **e** 601 module.

For more information, see *ProCell and CleanCell bottles* on page A-107.

► **To replace ProCell (PC)/CleanCell (CC) in case the green button is not flashing.**

1 Put the system in standby.

2 Open the middle door of the **e** 601.

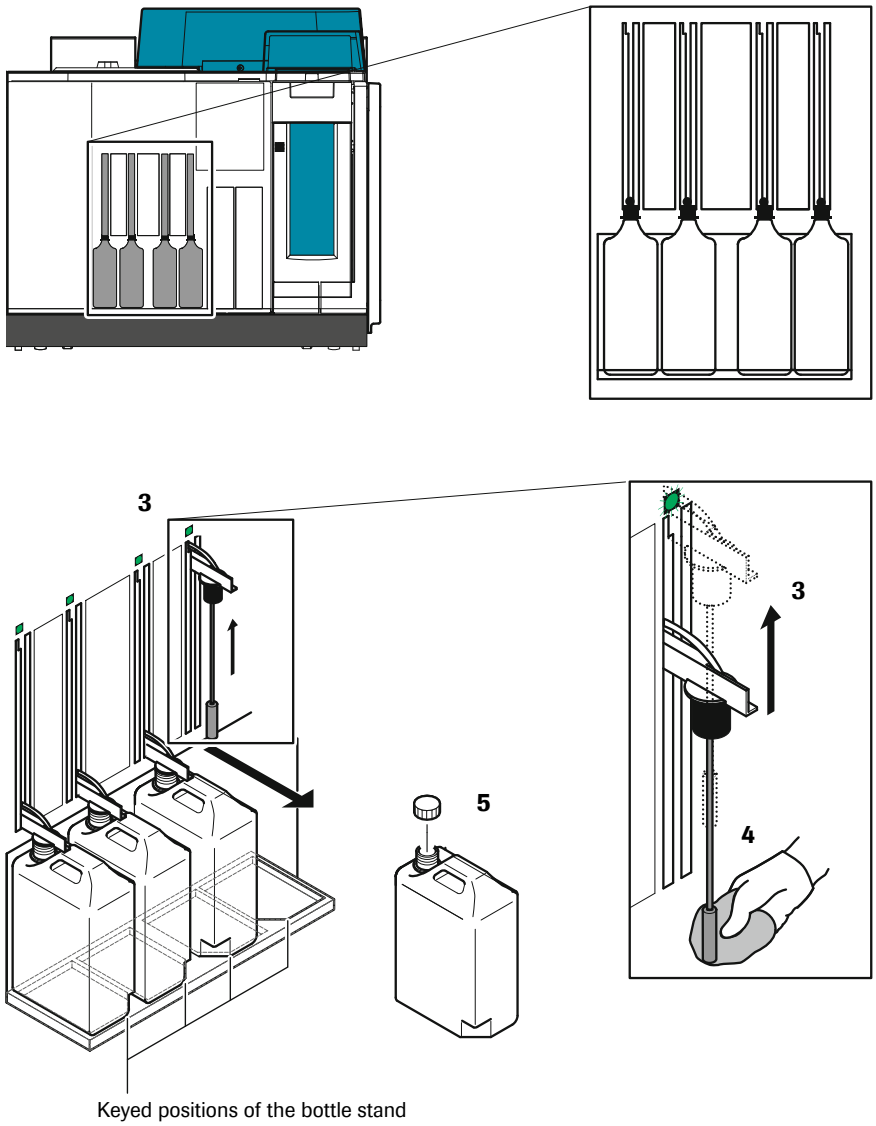


Figure B-69 Replacing ProCell/CleanCell bottles

CAUTION! False results due to loose ProCell/CleanCell aspiration tube filters. Make sure the aspiration tube is pulled up and hooked on to its notch, before removing the bottle. After replacing the bottle, unhook the aspiration tube and lower it slowly into the bottle, do not let it drop into the bottle.

3 Pull the aspiration tube up and to the left to secure them on their respective notches.

4 Absorb the liquid with lint-free gauze squares.

CAUTION! False results due to ProCell/CleanCell bottle misplacement. ProCell and CleanCell bottles are different in shape to fit the keyed position of the bottle stand. Ensure the bottle stand is present before placing the ProCell and CleanCell bottles.

5 Remove the expired bottle and replace it with a full bottle ensuring that it is firmly in place.

6 Lower the aspiration tube into the new bottle.

7 Press the green button corresponding to the position in which the new bottle has been placed to inform the system that a new bottle was loaded.

The light indication of the green button will be changed as follows:

Before pressing the button		After pressing the button	
Replaced set	**Opposite set**	**Replaced set**	**Opposite set**
Off (in use)	On (standby)	On (standby)	Off (in use)
Off (in use)	Flashing (empty)	Off (in use)	Flashing (empty)
On (standby)	Off (in use)	On (standby)	Off (in use)



Only press the green button after you have replaced a bottle. Do not press the green button under any other circumstances.

8 Close the middle door of the **e** 601.

9 If a ProCell bottle with a new lot number was loaded, enter the lot number on the **Reagent** > **Status** > **Inventory Setting**.

- Choose **Inventory Setting** to open the **Inventory Setting** window.
- Type the new lot number into the box for ProCell Position 1 or 2, respectively.
- Choose **Execute**.

■

Replacing PreClean when not empty

Two bottles of PreClean are located in the inner side of the front door of the module.

For more information, see *PreClean bottles* on page A-107.

► To replace PreClean in case the green button is not flashing

1 Put the system in standby.

2 Open the middle door at the front of the required module.

CAUTION! If you do not properly load the PreClean bottles the volume available for pipetting may be less than expected by the system and therefore cause deterioration in measurement accuracy.

3 Remove the expired bottle. Replace it with a full bottle ensuring that it is firmly in place and that the needle has pierced the bottle. Loosen the cap to allow air into the bottle.

4 Press the green button corresponding to the position in which the new bottle has been placed to inform the system that a new bottle has been loaded.

- In case the button is blacked out, it will be illuminated indicating that this is a standby bottle. The opposite button will be blacked out indicating that this bottle is in use.
- In case the button is lit already, it will be with no change indicating that this is a stand by bottle.



Only press the green button after you have replaced a bottle. Do not press the green button under any other circumstances.

5 Close the middle door of the **e** 601.

■

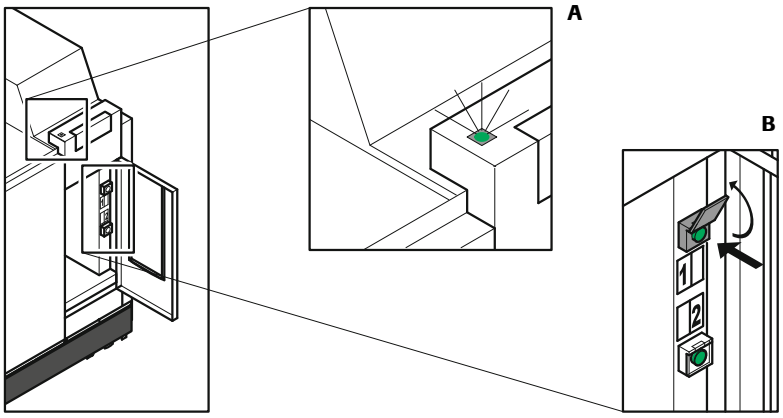
Replacing consumables and emptying solid waste (e 601)

All consumables (AssayCups and AssayTips) and solid waste are located in the magazine drawer, which consists of the magazine lifter, the magazine waste and the solid waste compartments.

- The lifter can be loaded with new AssayCup and AssayTip magazines.
- The magazine waste compartment contains the empty magazines.
- The solid waste compartment has solid waste containers.

See *Consumables area components* on page A-103.

The green indicator lamp on the top of the magazine drawer indicates when the magazine drawer and door can be opened. In addition, two green buttons to the right of the magazine lifter indicate when the waste containers can be accessed.



A Indicator lamp of the magazine drawer **B** Indicator lamps of the waste containers

Figure B-70 Indicator lamps of the magazine drawer and waste containers

Indicator lamp state	Indicator lamp (A) (magazine drawer)	Indicator lamp (B) (waste container)
Off		Waste container in use DO NOT replace
On	Drawer safe to open	standby container (empty) DO NOT replace
Flashing	About to operate DO NOT open	Container full, safe to be replaced Empty it immediately

Table B-19 Indicator lamp states of the magazine drawer and waste containers

► To replace AssayCup and AssayTip magazine

1. Pull out the drawer on the right hand side of the module fully.
2. Empty the magazine waste and refill the magazine lifter as required.
3. Close the drawer, ensuring that it is fully closed.
4. The level is checked and the inventory is automatically updated the next time the analyzer changes the magazine.

Ensure that the door at the front of the drawer is closed. Otherwise, the magazine lifter will detect the open door the next time it operates and the analyzer will stop.

■

► To empty solid waste

1. Pull out the drawer on the right hand side of the module fully.
2. Remove the waste container liners and replace with fresh ones as required.
3. Close the drawer, ensuring that it is fully closed.
4. Open the door at the front of the drawer.

Only press the green button after you have replaced a bottle. Do not press the green button under any other circumstances.

5. Press the flashing green button (to the right of the AssayCup and AssayTip tray magazine) corresponding to the container(s) emptied to update the system.
6. Close the door ensuring that it is fully closed.

Ensure that the door at the front of the drawer is closed. Otherwise, the magazine lifter will detect the open door the next time it operates and the analyzer will stop.

■

Reagent Overview button

By changing its color, the **Reagent Overview** button indicates potentially insufficient amounts of reagent on the module currently selected in the **Module Overview** area. It also indicates when QC results are out of range and if there is no valid calibration available:

Button in Module Overview area	Color	Meaning
Reagent Overview	Red	A reagent is empty and there is no second **cobas c** pack or **cobas e** pack on this particular module.
	Yellow	The number of tests remaining for a reagent is less than the yellow alarm level.
	Purple	The number of tests remaining for a reagent is less than the purple alarm level.

Table B-20 Colors of Reagent Overview button in Module Overview area

Choose this button to display the **Reagent Overview** window. This window displays an overview of the consumables loaded on the module currently selected.

Reagent Overview c 501 module

Select a **c** 501 module in the **Module Overview** area of the **System Overview** screen and choose **Reagent Overview** to display this screen. It consists of 3 areas, the **Reagent** area, **Inventory** area, and **ISE** area.

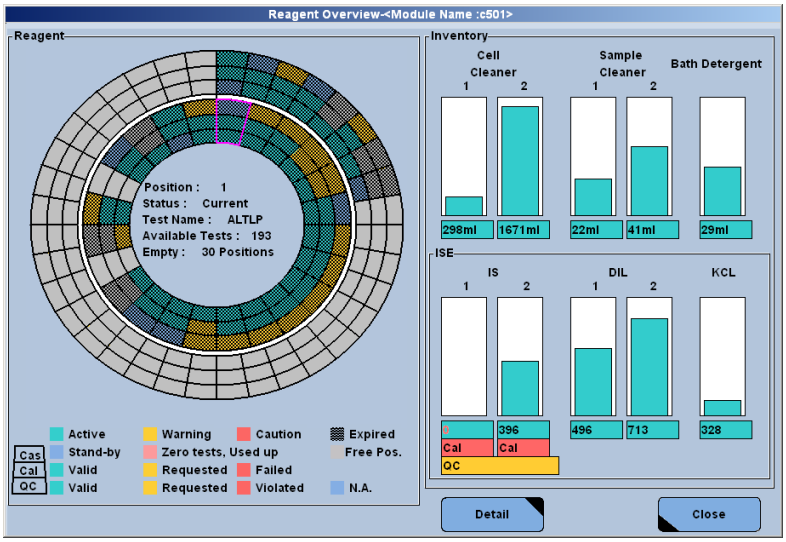


Figure B-71 Reagent Overview window (**c** 501 module)

A reagent mandatory message is displayed on the **Reagent Overview** screen if a mandatory reagent is not on board.

This function is available only if the test of the missing reagent has been defined as mandatory under the **Utility** > **Module Set** > **Test Assignment**.

Reagent area

Use this area to view the status of the **cobas c** packs, loaded on the module. This area comprises a graphic representing the reagent disk and a legend.

The graphic is divided into 2 large rings. Each of the large rings is subdivided into 3 subrings. The 24 segments of the inner large ring and the 36 segments of the outer large ring represent the 60 **cobas c** packs positions within the reagent compartment.

Each segment shows the following information:



- **Cas**: Reagent status (inner subring)
- **Cal**: Calibration status (middle subring)
- **QC**: QC status (outer subring)

Choosing a segment displays detailed information about the **cobas c** pack (**Position**, **Status**, **Test Name** and **Available Tests**) in the center of the graphic.

Legend The legend at the bottom of the **Reagent** area explains the colors represented in the segments of the reagent disk graphic.

1. Inner subring: **Cas** (Cassette = **cobas c** pack)

	Active	This **cobas c** pack is currently in use.
	Warning	Remaining tests in this **cobas c** pack set below yellow alarm level (**Utility** > **System** (**Page 2/4**) > **Reagent Level Check**).
	Caution	There is no more reagent available for this assay on this module.
	Stand-by	This **cobas c** pack is currently not in use.[(a)]
	Zero tests, Used up	The **cobas c** pack has been used up and is empty. There is still reagent available in another **cobas c** pack on this module.
	Free Pos.	There is no **cobas c** pack in this channel.
	Expired	The **cobas c** pack has exceeded its expiration date.

(a) Standby **cobas c** packs are already on board but not currently in use.

2. Middle subring: **Cal** (Calibration)

	Valid	A valid calibration is available.
	Requested	A calibration has been requested.
	Failed	The calibration of the **cobas c** pack has failed.

3. Outer subring: **QC** (Quality Control)

Valid	QC result is within the confidence limits.
Requested	A QC has been requested.
Violated	QC result is not within the confidence limits.
N.A.	Not applicable.

For diluent and cleaner **cobas c** packs, only the inner subring (**Cas**) contains information.

Reagent information

In the middle of the reagent disk, information about the selected **cobas c** pack is displayed.

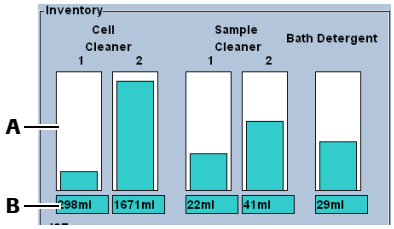
The following information is provided:

Position	Position of the **cobas c** pack in the reagent disk.
Status	Indicates that the **cobas c** pack is active or standby.
Test Name	Name of the **cobas c** pack.
Available Tests	Indicates the total number of determinations that can be measured with the currently available **cobas c** packs (including the standby **cobas c** packs). If a **cobas c** pack contains diluent or cleaner, the total volume is displayed in ml.
Empty	Number of empty positions on the reagent disk.

Reagent Overview button

Inventory area

The **Inventory** area displays the amount of auxiliary reagents on the module previously selected on the **System Overview** screen.



A Bar-chart for the remaining volume

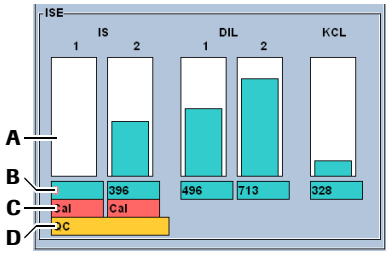
B Color-coded bar

Figure B-72 Inventory area of Reagent Overview window

Abbreviation	Unit	Color	Description
Cell Cleaner 1/2	mL		Cell Wash Solution I / NaOH-D and Cell wash Solution II / Acid Wash
		Yellow	Volume ≤ 50 mL
		Red	Bottle empty
Sample Cleaner 1/2	mL		Sample Cleaner 1 and Sample Cleaner 2
		Yellow	Volume < yellow alarm level
		Red	Bottle empty
Bath Detergent	mL		EcoTergent
		Yellow	Volume < yellow alarm level
		Red	Bottle empty

Table B-21 **c** 501 module reagent types

ISE area



A Bar-chart for the remaining number of tests
B Color-coded bar for the remaining number of tests that can be performed with the ISE reagents
C Color-coded bar for the calibration status
D Color-coded bar for the QC status

Figure B-73 ISE area of Reagent Overview window

The **ISE** area displays the amount of reagents using bar-charts (**A**). The first bar (**B**) below each bar-chart indicates the remaining number of tests for each ISE reagent. The second and the third bar below the bar-charts provide additional, color-coded information on the statuses of calibration (**C**) and QC (**D**).

If this field is empty after changing an ISE reagent bottle, the analyzer has not checked the remaining volume yet.

For information about remaining volume check, see *ISE reagent replacement* on page B-106.

Abbreviation	Unit	Description
IS	test	Internal standard solution
DIL	test	Diluent
KCL	test	Reference solution (ISE Ref.)

Table B-22 **c** 501 (ISE) reagent types

Two color-coded bars below the IS 1 and IS 2 bar-charts provide additional information on the statuses of calibration and QC.

1. First colored bar (directly below volume indication field): Calib

Valid	A valid calibration is available.
Requested	A calibration has been requested.
Failed	The calibration of the bottle has failed.

2. Second colored bar: QC

Valid	QC result is within the confidence limits.
Requested	Requested for QC measurement.
Violated	QC result is not within the confidence limits.
N.A.	Not applicable.

Detail window

Choose the **Detail** button to display the **Detail** window. This window displays more detailed information about the selected **cobas c** pack.

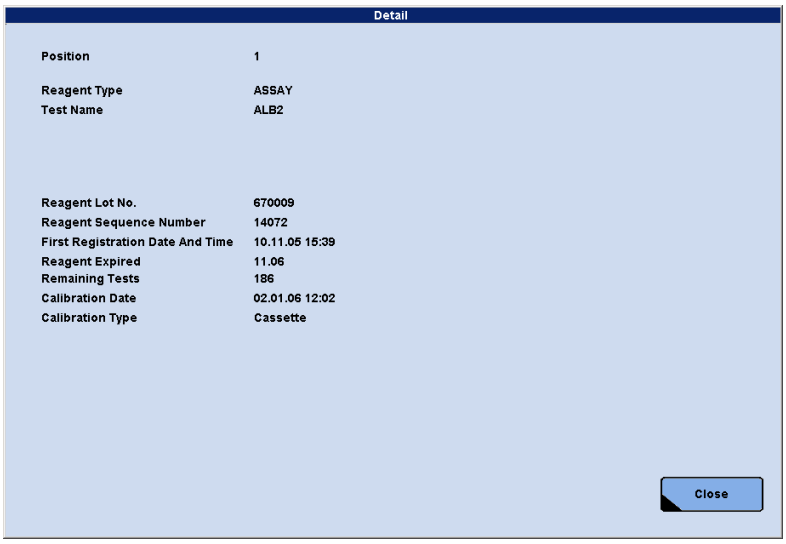
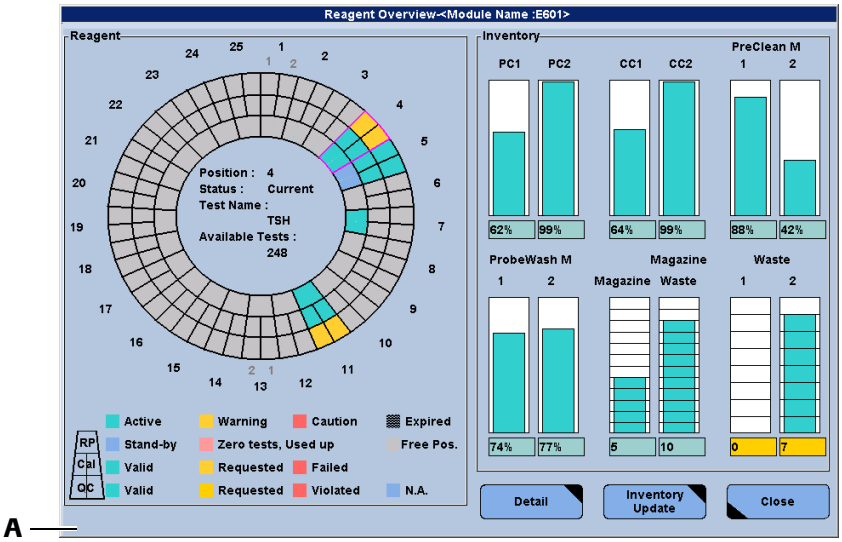


Figure B-74 Detail window (**c** 501)

For more information about the **Detail** window, see *Detail window* on page E-37.

Reagent Overview e 601 module

Select an **e** 601 module in the **Module Overview** area of the **System Overview** screen and choose **Reagent Overview** to display this screen. It consists of 2 areas, the **Reagent** area and the **Inventory** area.



A Reagent mandatory message

Figure B-75 Reagent Overview window (**e** 601 module)

A reagent mandatory message is displayed on the **Reagent Overview** screen if a mandatory reagent is not on board. This may occur if a reagent is not loaded or not available. The system will not start if this reagent is missing.

This function is available only if the test of the missing reagent has been defined as mandatory under the **Utility** > **Module Set** > **Test Assignment**.

Reagent area

Choosing a segment of the Reagent Disk graphic displays detailed information of the **cobas e** pack in the center of the graphic. The following information is displayed:

- **Position**
- **Status**
- **Test Name**
- **Available Tests**

The color of each segment corresponds to the status of the respective **cobas e** pack (inner ring), the status of the calibration (middle ring), and the status of the QC (outer ring). Segments of the middle and outer ring are subdivided in two subsections corresponding to the two measuring channels.

The legend at the bottom of the **Reagent** area explains the colors represented in the segments of the reagent disk graphic.

If the **e** 601 test is not assigned to both measuring cells, the subsection for the unassigned measuring cell is displayed in gray.

1. Inner ring: **RP** (**cobas e** pack)

Active	This **cobas e** pack is currently in use.
Warning	Remaining tests in this **cobas e** pack below yellow alarm level (**Utility** > **System** (**Page 2/4**) > **Reagent Level Check**).
Caution	There is no more reagent, diluent, or pretreatment available for this test on this module. A reagent or pretreatment **cobas e** pack is not linked to its required partner **cobas e** pack (link status **Free**). Partner **cobas e** pack is not on board.
Stand-by	This **cobas e** pack is currently not in use. Standby **cobas e** packs are already on board but not in use at present.
Zero tests, Used up	The **cobas e** pack has been used up and is empty. Reagent, diluent, or pretreatment for this test is still available in another **cobas e** pack on this module.
Free Pos.	There is no **cobas e** pack in this position.
Expired	The **cobas e** pack has exceeded its expiration date.

2. Middle ring: **Cal** (Calibration)

Valid	A valid calibration is available.
Requested	A calibration has been requested.
Failed	The calibration of the **cobas e** pack has failed.

3. Outer ring: **QC** (Quality Control)

	Valid	QC result is within the confidence limits.
	Requested	A QC has been requested.
	Violated	QC result is not within the confidence limits.
	N.A.	Not applicable.

Inventory area

This area displays the amount of auxiliary reagents, magazines, magazine waste and solid waste. The abbreviations have the following meanings:

Abbreviation	Unit	Description
PC1/PC2	%	ProCell bottle 1 and 2 One bottle empty ⇒ number box turns yellow Both bottles empty ⇒ number box turns red
CC1/CC2	%	CleanCell bottle 1 and 2 One bottle empty ⇒ number box turns yellow Both bottles empty ⇒ number box turns red
PreClean M 1/2	%	PreClean bottle 1 and 2 One bottle empty ⇒ number box turns yellow Both bottles empty ⇒ number box turns red
ProbeWash M 1/2	%	ProbeWash bottle 1 and 2 One bottle empty ⇒ number box turns yellow Both bottles empty ⇒ number box turns red
Magazine	Actual number (max 12)	Full magazine with AssayTips and AssayCups. Each full magazine ⇒ 1 blue box One magazine remaining ⇒ box turns yellow No magazines remaining ⇒ box turns red
Magazine waste	Actual number (max 12)	Empty magazine Each space available for empty magazine ⇒ 1 blue box Space for one empty magazine remaining ⇒ box turns yellow No space for empty magazines remaining ⇒ box turns red
Waste 1/2	Actual number in magazines	Solid waste for AssayTips and AssayCups. Each empty magazine ⇒ 1 blue box One solid waste remaining ⇒ box turns yellow No solid waste remaining ⇒ box turns red

Table B-23 Reagent and consumable types

Detail window

Choose the **Detail** button to display the **Detail** window. This window displays more detailed information about the selected **cobas e** pack.

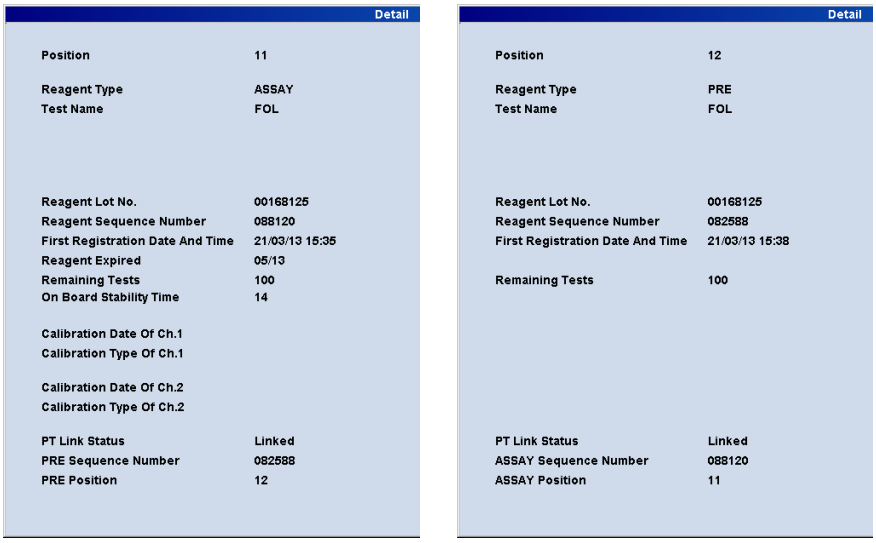


Figure B-76 Detail window of an assay and a pretreatment (**e** 601)

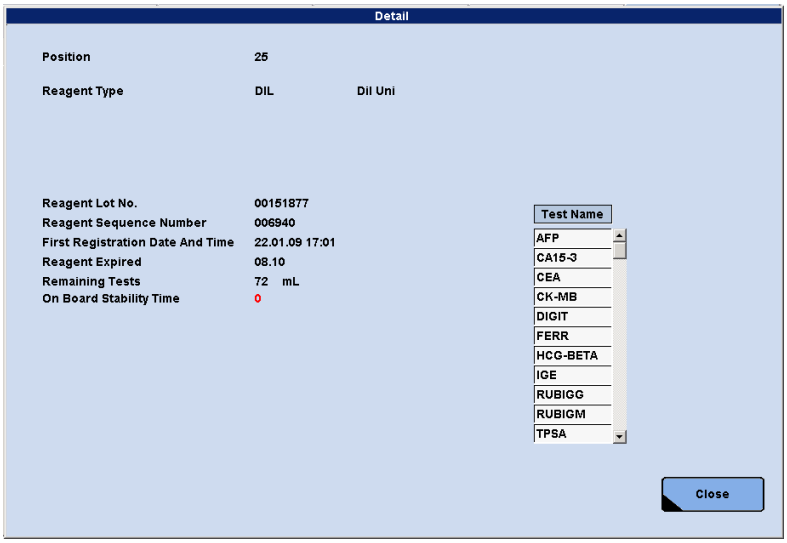


Figure B-77 Detail window of a diluent (**e** 601)

For more information about the **Detail** window, see *Detail window* on page E-37.

Inventory Update window

Use the **Inventory Update** button to execute an inventory update for an **e** 601 module.

This button is a shortcut to the **Inventory Update** maintenance window.

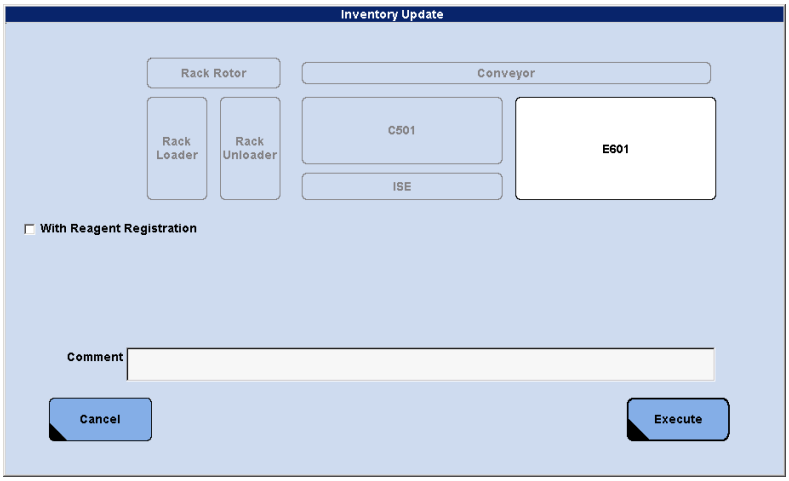


Figure B-78 Inventory Update window

If inventory update is executed the following actions are performed:

- Update the number of magazines in the magazine lifter
- Update the number of magazines on the magazine waste
- Check and update of ProbeWash solutions 1 & 2

The inventory update function is only available for **e** 601 module.

With Reagent Registration Select this check box to initiate a reagent registration as part of the inventory update.

Reagent Overview button

Calibration

This chapter provides descriptions of special tasks that are not usually part of the daily workflow. It is meant to complement the chapter Daily operation, where everyday tasks and common procedures for running the **cobas** 6000 analyzer are described.

In this chapter *Chapter* 11

Calibration concept B-155
Causes for automatic calibration recommendations B-156
Calibration concept – c 501 B-158
Calibration concept - ISE applications B-159
Calibration concept - photometric applications B-160
Lot and cassette calibrations for cobas c packs B-161
Calibration quality criteria for photometric applications B-161
Calibration concept – e 601 B-162
Lot and cassette calibrations for cobas e packs B-163
Calibration quality criteria for immunological applications B-164
Calibration concept – masking B-165
Overview B-166
Calibration Status screen B-166
Requesting and cancelling calibrations manually B-167
Reviewing calibration data B-169
Checking calibrations of photometric tests B-169
Checking calibrations of ISE tests B-173
Checking calibrations of e 601 tests B-174
Calibration factors (c 501) B-176
Selecting tests for start-up calibrations B-177
Calibration Calibrator screen B-178
Assigning calibrator positions B-178
Loading calibrator vials for e 601 tests B-180
Calibration Install screen B-181
Checking information about already installed calibrators B-182
Downloading or updating calibrator data B-184
Editing calibrator concentrations (c 501) B-189
Changing decimal places used for reportable data (c 501) B-191
ISE calibration B-193

System Overview screen B-194
Calibrating tests during operation B-194

Calibration concept

The following section gives an overview of the calibration concept applied by the **cobas** 6000 analyzer series; it provides a basic understanding of the various calibration functionalities implemented in the analyzer and its software.

For instructions on how to perform calibrations, see *Calibration and QC Select button* on page B-51.

What is calibration?

Calibration is the process that establishes a relation between measurement values (such as absorbance values or ECL signals) and the corresponding results (concentration of an analyte).

This process may comprise the complete setting up of a new calibration curve or it is only the update of one or two parameters of an existing calibration curve. In either case the term *calibration* is appropriate.

Automatic calibration

The relation between measurement values and results is subject to various environment and reagent conditions and may drift in the course of time. Therefore it is necessary to repeat calibrations regularly. To keep the resulting calibration management simple and efficient, the system automatically recommends calibrations.

To get an overview of the functionalities provided by the **cobas** 6000 analyzer series for automating calibration, refer to the following section.

See *Causes for automatic calibration recommendations* on page B-156.

Validation of calibration

After a calibration is performed, it needs to be validated. The system performs this task through automatic calibration checks. Whenever it detects an irregular condition or result, the calibration is classified as failed, a calibration alarm is issued, and the system recommends that calibration be repeated.

For a list of calibration alarms and for an overview of application-specific calibration quality criteria, see *Calibration quality criteria for immunological applications* on page B-164.

Information on the status of the calibrators that are currently processing can be viewed on the **Workplace** > **Calib. Review** screen.

See *Calib. Review screen* on page B-96.

Calibration masking

If a calibration fails one or more quality criteria applied in the validation process, tests should no longer be performed with the affected reagent. This is achieved automatically by means of the auto masking function.

For more information, see *Calibration concept – masking* on page B-165.

Causes for automatic calibration recommendations

The **cobas** 6000 system provides the following features:

- Automatic calibration at start-up of the analyzer. Manual calibration of a group of applications by selection of the **Start Up** button.
- Automatic calibration recommendation at change of reagents (Changeover calibration):

 Calibration at lot change of **cobas c** pack or **cobas e** pack
- Automatic calibration recommendation without reagent change:
 - Calibration at regular intervals (Timeout)
 - Calibration in combination with Preventive action (Calib Now)
 - Calibration due to QC out of range (QC-triggered calibration (QC Violation))
- Automatic recommendation for recalibration when a calibration failed (Failed)

The different calibration functions can be combined. For automatic calibration without reagent change, you have to decide on one workflow: Timeout calibration or QC violation.

Start-up calibration

With this function you can select a predefined set of tests that are calibrated when you order a start-up calibration manually. The tests for Start up calibration are defined on **Calibration** > **Status** > **Start Up Setting**.

See *To select tests for start-up calibration* on page B-177.

Changeover calibration

Calibrations also have to be performed when the following events occur:

- A change in reagent lot (of **cobas c** packs or **cobas e** packs) takes place.
- A change in a **cobas c** pack (regardless of the lot). This depends on the setting in **Utility** > **Application** > **Calib**.
- At installation of a new test on the system

Timeout

Calibrations are performed at regular intervals to compensate for changes over time in reagents and in the measurement systems. Timeout calibrations can be performed for lot or cassette calibration.

A cassette calibration is displayed in the software and on the reports as **R.Pack** calibration.

QC-triggered calibration (QC Violation)

Calibration recommendation will be initiated if the QC results are outside the confidence limit. Up to three different controls can be defined.

For each application you have to decide whether calibration should be performed time-triggered (Timeout) or QC-triggered (QC violation).

It is recommended to decide on one calibration workflow. Either time-triggered or QC-triggered calibration should be defined for all applications.

When a new application is loaded, time-triggered calibration is the default setting and the intervals recommended by Roche Diagnostics are predefined. If you prefer a workflow with QC-triggered calibration, you have to activate **QC Violation**.

For information on the necessary QC violation settings, see *Auto calibration* on page B-265.

Calib Now

This automatic calibration function is active only if **Preventive Action** is activated. When a calibration times out during the period specified in the **Remaining Time** box on the **Calibration** > **Status** screen, the system recommends a calibration indicating *Calib Now* as calibration cause.

Calibration concept – c 501

This section describes the calibration concept for ISE and photometric applications.

General calibration rules

The general calibration rules are listed below:

- Calibration is best done as part of the daily preroutine operation. However, it can be done at any time during operation as well.
- Multi-analyte calibrators are usually used. Calibrator data are downloaded via **cobas** link.
- Expired calibrators should not be used. If expired calibrators are used, no alarm is issued.
- Calibrations are carried out in duplicate.
- Barcoded calibrators:

 Roche Diagnostics calibrators are always supplied with barcode labels (inserted in the calibrator kit). The labels must be placed on a tube.

 A barcode for water is also available but must be ordered separately.
- Non-barcoded calibrators can be used as well. In this case calibrator vials have to be assigned to specific racks and positions (rack assignment).
- Calibrators can be used several times for calibrations.
- If calibration is recommended due to QC violation the control material can be run again. If the controls are then within their confidence limits, the calibration recommendation is removed.

Positioning of calibrators

Calibrators are placed in calibrator racks (black racks).

- Non-barcoded calibrators have to be assigned to specific racks and positions.

 See *Assigning calibrator positions* on page B-178.
- Barcoded calibrators and their racks must not have a rack assignment.
- Barcoded and non-barcoded calibrators must not be placed on one rack. These racks may not be processed correctly by the system.

Calibration concept – ISE applications

Full calibration

Full calibration for Na^+, K^+, and Cl^- requires the following three calibrator solutions:

Product name	Short name used in this documentation	Short name used in the software	Calibration method	Code
ISE Standard low	ISE Low	Std (1) or S1	two-point or full	502
ISE Standard high	ISE High	Std (2) or S2	two-point or full	503
ISE Standard high	ISE High	Std (3) or S3	blank or full	763

Table B-24 Calibrators for ISE

The slope of the calibration curve is calculated from ISE Standards 1 and 2.

A full calibration is required at least every 24 hours.

One-point calibration

The ISE internal standard (ISE IS) is measured before and after each routine sample (only one measurement for sample analyses in succession). These measurements are used to correct for system-related drift (junction potential differences, differences in electrode conditions, etc.).

The ISE IS is measured during calibration as well.

Sample type specific ISE calibration curves

It is possible to set up and use two independent sets of calibration curves (**Type A** and **Type B**) for different sample types for Na^+, K^+, and Cl^-.

If only one calibration curve is used for the different sample types, only one calibration is performed.

For information on configuration and assignment of calibrations, see:
Setting up individual calibration curves for each ISE sample type on page B-276
ISE calibration on page B-193.

Calibration concept – photometric applications

Types of calibration curves

There are six different types of calibration curves possible on **c** 501 modules. One of six different types of mathematical functions is used to describe the relation between a measured value and a result.

In this document and in the user interface (UI), these types of calibration curves are called calibration types. The names of the calibration types are:

Linear	RCM2T1	Spline
RCM	RCM2T2	Line Graph

Table B-25 Calibration types for photometric tests

Each calibration type corresponds to one type of mathematical function. For example, *Linear* corresponds to a linear equation, *RCM2T2* to an exponential function.

For more details, refer to the *COBI-CD*.

Calibration curve parameters

A specific calibration curve is defined by its calibration type (mathematical function) and its parameters. The names of these parameters in the user interface are:

S1Abs., K, A, B, and C.

A Linear calibration curve, for example, is defined by two parameters (S1Abs. and K), an RCM calibration curve is defined by four, and a Spline can require up to six parameters. When the system performs a calibration, it redetermines these parameters by fitting the calibration curve to the newly measured values.

Calibration methods

Calibrations are performed with varying numbers of calibrators. Up to six calibrators are used for a full calibration of certain photometric tests. However, not all calibrators available for a test need to be used in every calibration. To define which calibrators are used, there is a choice of up to four different calibration methods.

The availability of calibration methods depends on the kind of test to be calibrated. The Table B-26 displays all calibration methods and the corresponding calibrators.

	Photometric tests	**ISE tests**
Blank	Std (1)[(a)] is used	Only ISE High [Std (3)] is used
Span	Only one calibrator out of Std (2)-Std (6)[(b)] is used	Not available
2 Point	Std (1) and a second calibrator are used	ISE Low [Std (1)] and ISE High [Std (2)] are used
Full	All calibrators [Std (1)-Std (6)] are used (for nonlinear calibration types)	ISE Low [Std (1)], ISE High [Std (2)], and ISE High [Std (3)] are used

Table B-26 Calibration methods on **c** 501 module

(a) Std (1) is the first standard solution, that is, the calibrator of the lowest analyte concentration. For many photometric applications, water is used as a blank calibrator.

(b) Std (2)-Std (6) refer to calibrators assigned to an application under **Utility** > **Application** > **Other**.

Lot and cassette calibrations for cobas c packs

Lot calibration

Lot calibration data are reagent lot specific for each test. Lot calibration data are transferred to other **cobas c** packs belonging to the same reagent lot. The lot calibration data are applied to result calculations for all patient samples and controls using **cobas c** packs of the same lot after a valid lot calibration was generated.

A lot calibration can only be generated from a *fresh* **cobas c** pack (one that was not previously on the instrument). The calibration must be performed within 24 hours after the **cobas c** pack has been registered by the instrument.

Do not use expired **cobas c** packs. Lot calibrations cannot be generated with expired **cobas c** packs. Calibrations with expired **cobas c** packs will be released as cassette calibrations only.

Cassette calibration

The cassette calibration data are **cobas c** pack-specific. A cassette calibration is generated when a **cobas c** pack is calibrated after it has been on board longer than 24 hours after registration.

A cassette calibration is also generated when an expired **cobas c** pack is calibrated within 24 hours after registration.

A cassette calibration is displayed as **R.Pack** calibration in the **Calibration** > **Status** screen.

Newest calibration

Newest calibration is a function that permits replacement of empty **cobas c** packs during operation without performing a calibration.

For a **cobas c** pack for which no calibration data exists, the newest calibration result is transferred at the time of its registration. This function is used to avoid the following situation: A **cobas c** pack of a new lot that was loaded on the instrument does not have any calibration data. The newest calibration data (the data of the last valid lot calibration) are transferred to this new lot.

Calibration quality criteria for photometric applications

Calibration measurements are automatically checked against various quality criteria. These criteria are test-specific and therefore the corresponding limit values are individually set for each photometric application.

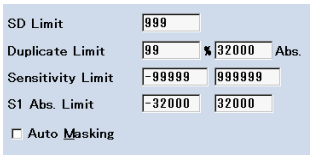


Figure B-79 **Calib.** tab on **Utility** > **Application** screen

Calibration concept – e 601

Calibration is the process that establishes a relation between measurement values (such as ECL signals) and the corresponding results (concentration of an analyte). This relation depends on both analyzer conditions and reagent conditions. For this reason, Roche Diagnostics supplies a master calibration curve for each application (generated during production of the reagent kit) and—at the customer's site—the analyzer generates an adjustment of this master calibration curve under the local routine laboratory conditions.

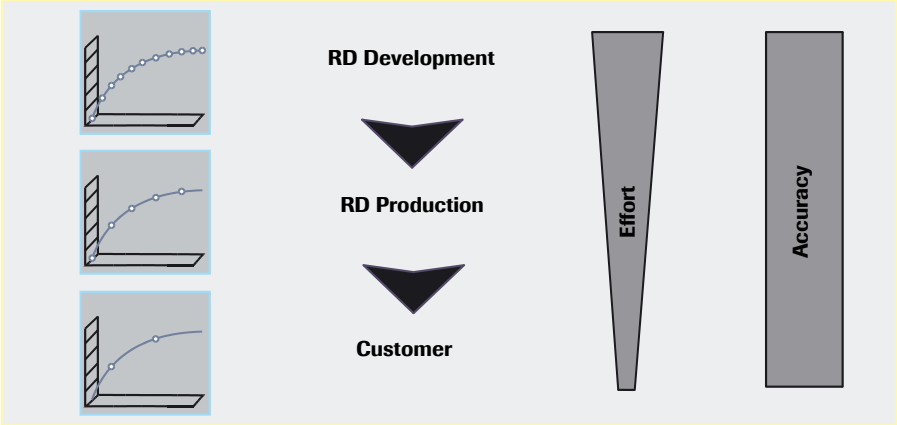


Figure B-80 Calibration concept **e** 601

General calibration rules

The general calibration rules are listed below:

- Calibration is best done as part of the daily preroutine operation. However, it can be done at any time during operation as well.
- Test-specific calibrators are used. Calibrator data are downloaded via **cobas** link or they are encoded within the **cobas e** pack barcode.
- Calibrations are carried out in duplicate.
- Expired calibrators cannot be used.
- If calibration is recommended as QC violation because of results out of confidence limit, the control material can be run again. If the controls are then within their confidence limits, the calibration recommendation is removed.

Positioning of calibrators

Calibrators are placed in calibrator racks (black racks).

Important: Do not separate the vials of a calibration set. They have to be in consecutive positions.

Limitation of calibration events

Each calibrator vial barcode can be used for a maximum of four calibration events. After that, the analyzer does not accept the calibrator vial and will not perform the calibration. A calibration of a measuring cell is one calibration event.

Valid calibrator lots

Every **cobas e** pack lot is linked to 5 calibrator lots. The valid lot numbers are encoded in the **cobas e** pack barcode.

It is possible to download calibrator data for non-valid calibrator lots. A calibration with a non-valid calibrator lot is not possible.

Inpack calibrator

Some tests for the **cobas e** 601 are delivered together with a calibrator, a so-called inpack calibrator. An inpack calibrator can only be used for the corresponding **cobas e** pack lot.

Inpack calibrators are installed by scanning the **cobas e** pack barcode during reagent registration. Downloading of calibrator data from **cobas** link is not possible. Up to five calibrator lots can be stored for an inpack calibrator.

Delete inpack calibrators which are not in use anymore before using new once.

Lot and cassette calibrations for cobas e packs

Lot calibrations

Every new reagent lot must be calibrated. A lot calibration is generated if a calibration is carried out within 24 hours (from first registration of the **cobas e** pack on the **e** 601 module) and all calibration criteria are met.

- Calibrations are measuring cell-specific, that is, each measuring cell has to be calibrated separately.
- Once a lot calibration has been accepted, it is automatically used for all **cobas e** packs of the same lot that are registered afterwards.



Do not use expired **cobas e** packs. Lot calibrations cannot be generated with expired reagents. Calibrations with expired reagents will be released as cassette calibrations only.

Cassette calibrations

A calibration automatically becomes a cassette calibration if the **cobas e** pack has been on the module for longer than 24 hours before the calibration is performed.

A cassette calibration is also generated when an expired **cobas e** pack is calibrated within 24 hours after registration.

The generated calibration curve is only valid for the **cobas e** pack from which it was measured (**cobas e** pack number specific).



A cassette calibration is displayed in the software and on the reports as **R.Pack** calibration.

For more details, refer to the *COBI-CD*.

Calibration quality criteria for immunological applications

Calibration measurements are automatically checked against various quality criteria. The assessment is different for qualitative and quantitative assays. The following table shows which criteria are used for quantitative assays and which are used for qualitative assays.

Results of the calibration checks are displayed in the **Calibration Result** (Immune) window. To open this window, select an **e** 601 test from the **Calibration** > **Status** screen and choose **Calibration Result**.

Quantitative assays	Qualitative assays
Missing values	Missing values
Monotony of curve	Slope
Minimum signal	Minimum signal
	Maximum signal
Minimum difference	Minimum acceptable difference
Deviation of duplicate measurement	Deviation of duplicate measurement
System error	System error, calibration factor
Calibration factor	

Table B-27 Quality criteria for quantitative and qualitative assays

For more details, refer to the *COBI-CD*.

Calibration concept – masking

Automatic calibration masking is a function that masks a **cobas c** pack or **cobas e** pack for a module or measuring cell when no valid calibration is available for this particular module or measuring cell.

This function is activated (or deactivated) for the entire system under **Utility** > **System** (**Page 2/4**) > **Calib Mask Setting**. When activated, the function can be selected individually for each application on the **Calib.** tab of the **Utility** > **Application** screen. This setting is set as the default in the applications.

See *Auto masking* on page B-265.

Failed calibrations

When a calibration is successful, the calibration data are available for the measurement of patient samples and controls. When a calibration fails one or more quality criteria, this calibration gets the status *Failed*. *Failed* calibration data is not available for the corresponding **cobas c** pack or **cobas e** pack.

If automatic calibration masking is activated, the corresponding test with the *Failed* calibration is masked. If automatic calibration masking is not activated, the test is not masked but data alarms are attached to the results.

cobas c pack changeover

When a changeover request is present and automatic calibration masking is not activated, this **cobas c** pack will work with the last valid lot calibration data for this test (newest calibration). No alarm is attached to this result.

See *Newest calibration* on page B-161.

Reject button

A *Failed* calibration can be *rejected* by the operator (**Reject** button on **Calibration** > **Status**) so that the latest successful calibration, if it exists, is used for the upcoming samples and controls.

Overview

The calibration menu contains three screens: **Calibration** > **Status**, **Calibration** > **Calibrator**, and **Calibration** > **Install**. This chapter describes important commands accessed via these screens as well as various information displayed on them.

However, this chapter does not cover all possible commands. For a complete description of all fields of the software's user interface, refer to the *Online Help*.

For more information about the calibration menu, see *Calibration menu* on page E-265.

Calibration Status screen

The following sections explain certain tasks associated with the **Calibration** > **Status** screen. Not all tasks are described, but the most important ones.

To display this screen choose **Calibration** > **Status**.

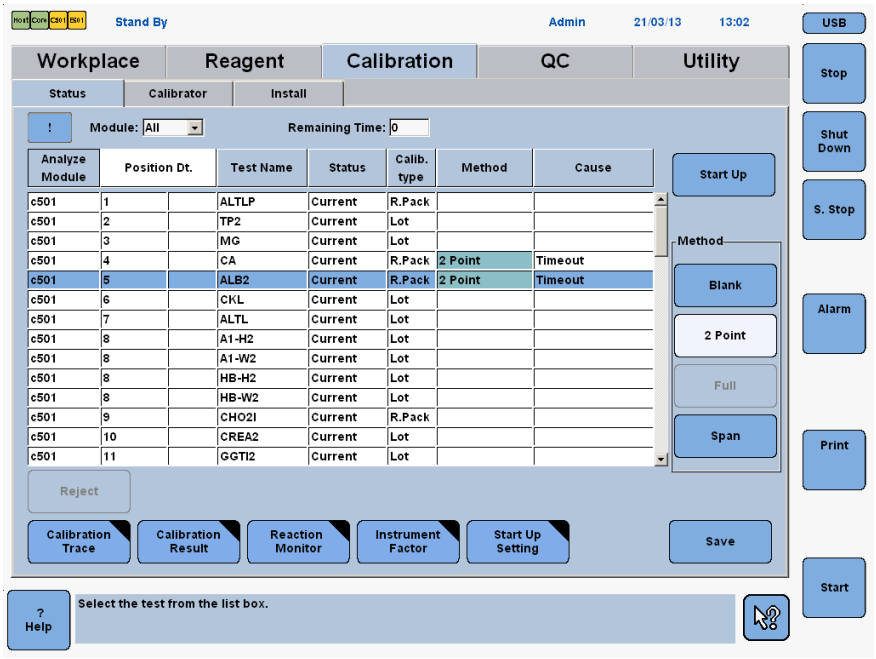


Figure B-81 Calibration > Status screen

This screen shows detailed information about the calibration status of the tests on the modules selected in the **Module** list box. This screen is used to select tests for start up, timeout, changeover or manual calibrations.

For more information about the calibrator status during calibration, see *Calib. Review screen* on page B-96.

Exclamation Point button This button turns yellow if the displayed status list should be updated. The displayed information may be out-of-date, for example, if a calibration has been performed in the meantime. Choose the **Exclamation Point** button to update the status list.

For information about particular tasks associated with this screen, see:
Requesting and cancelling calibrations manually on page B-167
Reviewing calibration data on page B-169
Calibration factors (c 501) on page B-176
Selecting tests for start-up calibrations on page B-177

Exclamation Point button This button turns yellow if the displayed status list should be updated. The displayed information may be out-of-date, for example, if a calibration has been performed in the meantime. Choose the **Exclamation Point** button to update the status list.

Requesting and cancelling calibrations manually

According to the intended use, calibrations are automatically recommended by the system and accepted by the operator via the **System Overview** screen.

See *Calibration and QC Select button* on page B-51.

Regardless of these system recommendations calibrations can be manually selected and deselected as well.

► To request calibration for a test manually

1 Choose **Calibration** > **Status**.

2 Select the test and reagent (**Current** or **SBx**) that needs to be calibrated from the list.

The selected line is highlighted in blue.

Missing test in status list

A test only occurs in the status list if the corresponding **cobas c** pack or **cobas e** pack is on board.

3 Select the appropriate button in the **Method** area for a **Blank**, **2 Point**, **Full**, or **Span** calibration.

The selected option appears in the **Method** column highlighted in green, the **Cause** column indicates **Manual**, and the **Save** button turns yellow.

4 To request calibrations for additional reagents and tests repeat steps 2 and 3.

5 Choose **Save** to save the changes.

All listed tests and reagents that have an entry in the **Method** column are highlighted in green. This corresponds to a requested calibration.

In case there are reagents with less than 10 tests on board, a confirmation window opens and it is possible to cancel the calibration or QC request for these reagents.

■

► To reset a manual requested calibration

1 Choose **Calibration** > **Status**.

2 Select the reagent and test for which the calibration request should be reset.

The selected line is highlighted in blue, the entry in the **Method** column is highlighted in green, and the corresponding button in the **Method** area is highlighted in white.

3 Select the white highlighted button in the **Method** area.

The entries in the **Method** and **Cause** column for this reagent disappear and the **Save** button turns yellow.

4 To reset further calibration requests repeat steps 2 and 3.

5 Choose **Save** to save the changes.

■

Reviewing calibration data

After a calibration is completed it should be reviewed. Details for each calibration performed on any of the analyzer's modules can be retrieved from the **Calibration** > **Status** screen. The following sections describe the possibilities to check calibration data according to the different kinds of test calibrated.

For further information, see:
Checking calibrations of photometric tests on page B-169
Checking calibrations of ISE tests on page B-173
Checking calibrations of e 601 tests on page B-174

Checking calibrations of photometric tests

For each successful calibration of a photometric test, the following information is available:

- **Calibration Factor**: Parameters that determine the position and shape of the calibration curve.

 See *Calibration factors (c 501)* on page B-176.
- **Working Information** (calibration curve): Mathematical relation between the measured signal (for example, absorbance or rate of change in absorbance) and the corresponding concentration value for the concerned analyte.
- **Reaction Monitor**: A graph showing the measured absorbance in the course of a test measurement.
- **Calibration Trace**: A graph used to review the measurements of the 50 most recent calibrations for a specific test. It shows signal values for both, the Std (1) calibrator and the calibrator with the maximum concentration on one plot.

► To review calibration data

1 Choose **Calibration** > **Status**.

2 Select a photometric test from the list on **Calibration** > **Status**.

3 Choose **Calibration Result** to display the **Calibration Result** window.

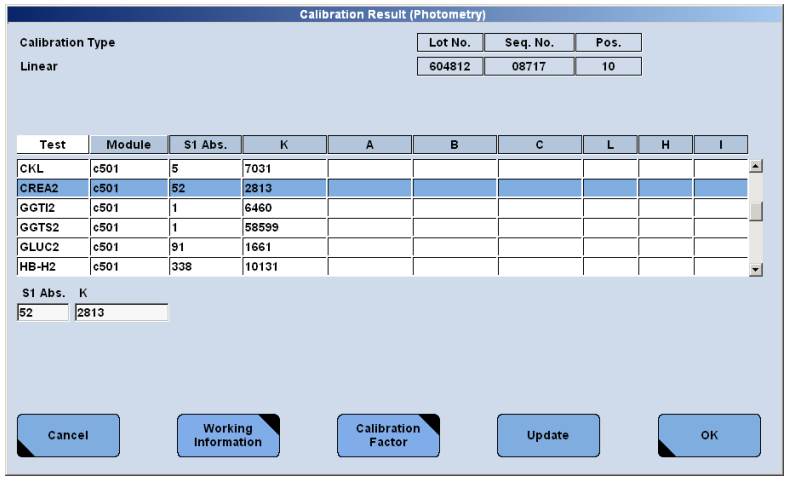


Figure B-82 Calibration Result (Photometry) window

This window gives information about the most recent calibrations for the displayed photometric test.

- To display the calibration curve of a selected test choose **Working Information**.
- To display the calibration factors for the cassette calibration, lot calibration, and currently valid calibration of a selected test choose **Calibration Factor**.

 For more details, see *Calibration factors (c 501)* on page B-176.

■

► To review measurement details of the most recent calibration (c 501)

1 Choose **Calibration** > **Status**.

2 Select a photometric test from the list on **Calibration** > **Status**.

3 Choose **Reaction Monitor** to display the **Reaction Monitor** window.

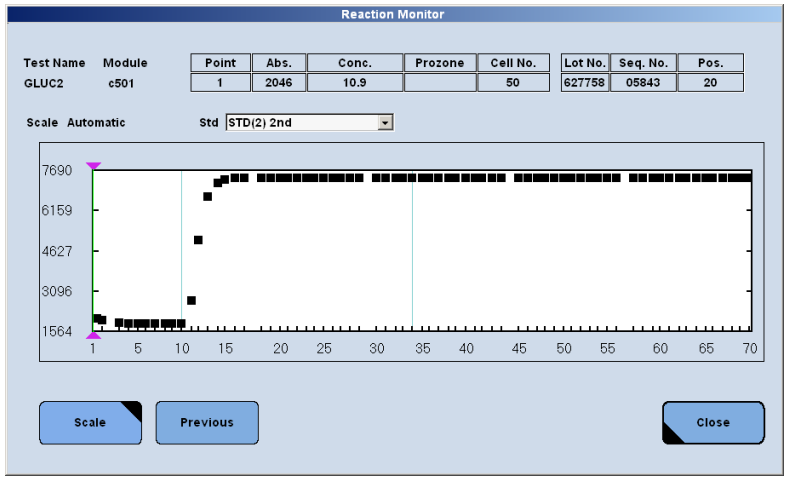


Figure B-83 Reaction Monitor window

This window displays reaction graphs for each of the duplicate measurements of each calibrator used for the calibration selected.

4 Use the drop-down list above the graph to select a specific measurement. The extensions *1st* and *2nd* in the list correspond to the first and second measurement of each calibrator, respectively.

For more details, refer to the *COBI-CD*.

■

Reaction monitor data of a calibration can be printed out: First, select a test from the **Calibration** > **Status** screen, then, choose **Print** (global button) > **Work Place,** select **Reaction Monitor** from the list on the left, and choose **Print**.

► To view and compare results of previous c 501 calibrations

1 Choose **Calibration** > **Status**.

2 Select a photometric test from the list on **Calibration** > **Status**.

3 In order to view and compare the results of previous calibrations of the selected test, choose **Calibration Trace**.

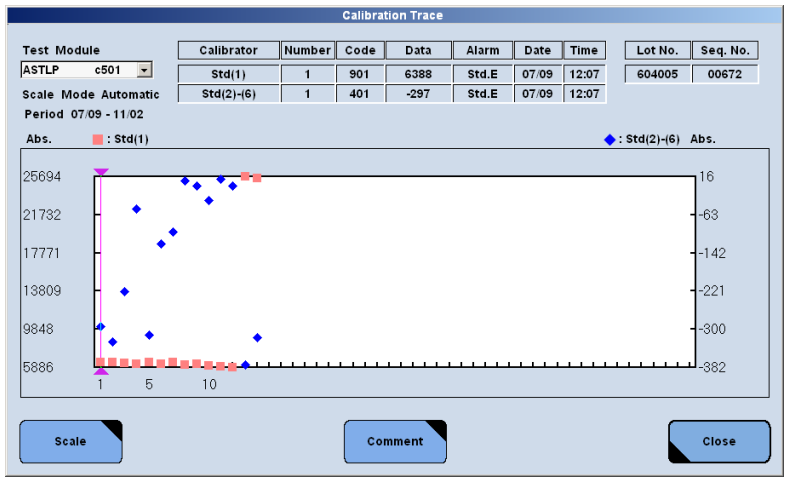


Figure B-84 Calibration Trace window

The graph shows calibration results for the selected photometric test. It displays the measured absorbance values for both the Std (1) calibrator and the calibrator with the maximum concentration Std (2)-Std (6) on one plot.

The left and right Y-axes are scaled independently:

- The left axis refers to the Std (1) calibrator represented by ■.

 In case of a rate assay, it indicates the primary wavelength absorbance at photometric measuring point 1 of Std (1).

- The right axis refers to the maximum calibrator Std (2)-Std (6) represented by ◆.

■

The **Comment** button is to enter a comment to this trace. However, it applies to all events, it is not event specific. This means when entering a comment specific to this enter the date and time you entered this comment.

The calibration trace can be printed out. First, select a test from the **Calibration** > **Status** screen, then, choose **Print** (global button) > **Calibration**, select **Calibration Trace** from the list on the left, and choose **Print**.

Checking calibrations of ISE tests

For each successful calibration of an ISE test, the following information is available:

- **Calibration Result (ISE)**: Results from the most recent successful ISE calibration for the test selected.
- **Calibration Trace**: A graph used to review the measurements of the 50 most recent calibrations for a specific test. It shows both the measured data for the selected test's Std 3 ISE High (in mmol/L) and slope values (in mV) on one plot.

► To review ISE calibration data

1 Choose **Calibration** > **Status**.

2 Select an ISE test from the list on **Calibration** > **Status**.

The entries ISE-A and ISE-B refer to two different calibration curves that can be assigned to different sample types. For example, ISE-A is assigned to serum/plasma and ISE-B to urine samples. This assignment is set on **Utility** > **System** (**Page 3/4**) > **ISE Calib Setting**.

3 Choose **Calibration Result** to display the **Calibration Result (ISE)** window.

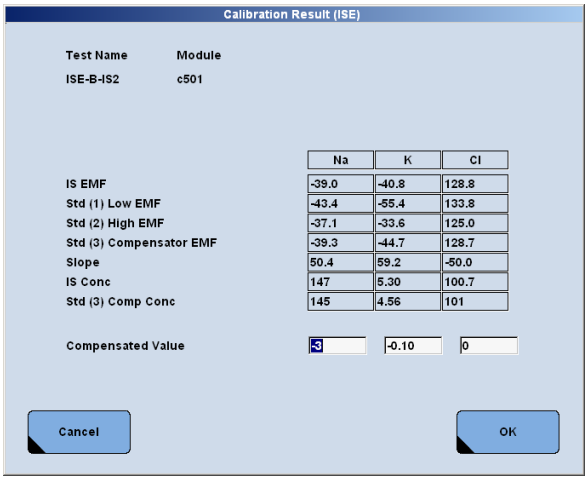


Figure B-85 Calibration Result (ISE) window

This window displays information about the most recent successful ISE calibration: electromotive force (EMF), slope, and target concentration values.

The three **Compensated Value** text boxes display the difference between the target value of ISE Std (3) (ISE High) and its measured values for Na^+, K^+, and Cl^-. This difference is added to all measured routine samples and controls.

The slope of the calibration curve is calculated from ISE Standards 1 and 2. ISE Standard 3 affects the intercept and not the slope.

■

► To review results of previous ISE calibrations

1 Choose **Calibration** > **Status**.

2 Select an ISE test from the list on **Calibration** > **Status**.

3 Choose **Calibration Trace** to open the **Calibration Trace** window.

4 Select a test from the drop-down list on the top left of the window.

The graph shows calibration results for the selected ISE test. The left and right Y-axes are scaled independently:

- The left axis refers to the measured concentration values of the ISE Standard 3 represented by ■.
- The right axis refers to the calculated slope values represented by ◆.

■

Checking calibrations of e 601 tests

For each successful calibration of an **e** 601 test, the following information is available:

- **Calibration Results (Immune)**: A list showing target and signal values for the selected test on the **Calibration** > **Status** screen.
- **Calibration Trace**: A graph used to review the measurements of up to 50 recent calibrations for a specific test. It shows signal values for both calibrators on one plot.

► To review e 601 calibration data

1 Choose **Calibration** > **Status**.

2 Select a **cobas e** pack and the corresponding measuring cell from the list on **Calibration** > **Status**.

3 Choose **Calibration Result** to display the **Calibration Result** window.

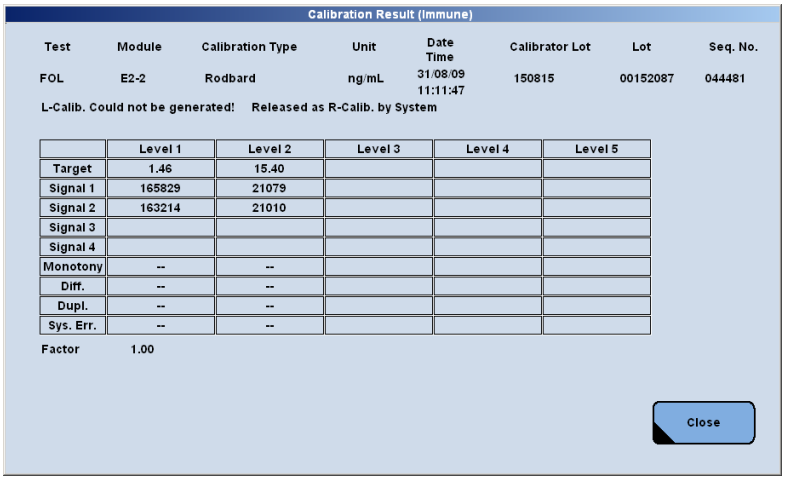


Figure B-86 Calibration Result (Immune) window

This window displays used calibration information for the selected **cobas e** pack (signal levels, calibration criteria).

■

► To view and compare results of previous e 601 calibrations

1 Choose **Calibration** > **Status**.

2 Select a **cobas e** pack and the corresponding measuring cell from the list on **Calibration** > **Status**.

3 Choose **Calibration Trace** to open the **Calibration Trace** window.

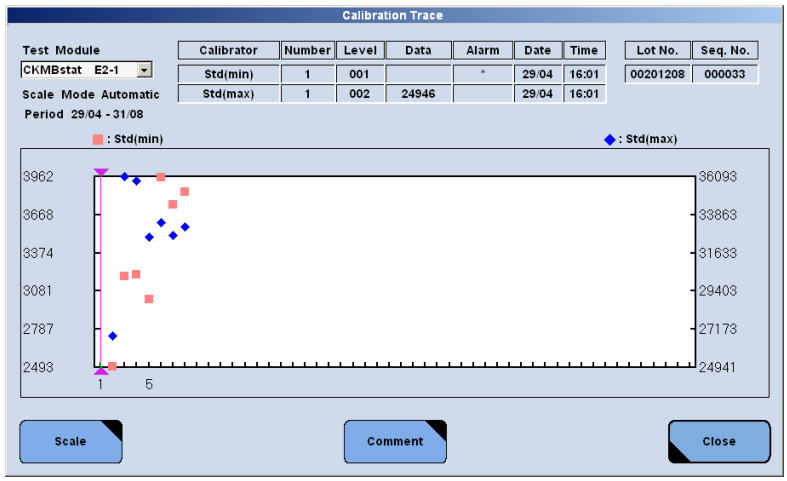


Figure B-87 Calibration Trace window for **e** 601 tests

The graph shows calibration data for the selected test and measuring cell. It displays the mean of the measured signal values for both the low concentration calibrator, Std (min), and the high concentration calibrator, Std (max), on one plot.

The left and right Y-axes are scaled independently:

- The left axis refers to the Std (min) calibrator, represented by ■.
- The right axis refers to the Std (max) calibrator, represented by ◆.

4 If you want to switch to the other measuring cell or another test select from the **Test Module** list box the corresponding test and measuring cell.

The list box displays the test name, the short name of the module and the measurement cell.

■

The calibration trace can be printed out. First, select a test and measuring cell from the **Calibration** > **Status** screen, then, choose **Print** (global button) > **Calibration**, select **Calibration Trace** from the list on the left, and choose **Print**.

Calibration factors (c 501)

The term calibration factors refers to coefficients (S1Abs, K, A, B, C) used for setting on calibration curves for photometric tests. The system stores calibration factors for each calibration curve of all registered reagent cassettes. The following kinds of calibration factors are available: **Cassette**, **Lot**, and **Newest**.

For more information, see *Lot and cassette calibrations for cobas c packs* on page B-161.

► To check calibration factors

1 Choose **Calibration** > **Status**.

2 Select a photometric test from the test list.

3 Choose **Calibration Result**.

4 On the **Calibration Result** window, choose **Calibration Factor**.

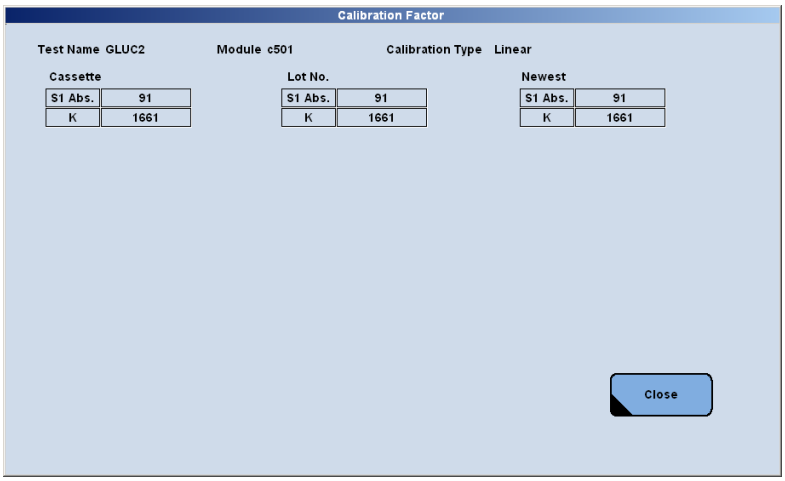


Figure B-88 Calibration Factor window (**c** 501)

The **Calibration Factor** window opens. On the **Calibration Factor** window you can see which calibration is currently used for calculating the results.

■

Cassette The factors of the selected **cobas c** pack which are used for calculating the results are displayed.

If a cassette calibration is used for calculating the results, the factors of cassette differ from the factors of the lot calibration.

If a lot calibration is used, the factors of cassette are the same as the factors of the lot calibration.

Lot No. The factors of the lot calibration are displayed.

Newest The factors used for the newest calibration is displayed. Always the last valid lot calibration is used as the newest calibration.

The newest calibration is transferred to a cassette for which no valid lot calibration exists and that has not been calibrated since loading.

Selecting tests for start-up calibrations

The start-up calibration function allows a set of tests to be calibrated at the same time:

- Tests selected for start-up calibration will be requested as soon as the **Start Up** button in **System Overview** > **Calibration and QC Select** screen is chosen.
- You can also request a start-up calibration by choosing **Calibration** > **Status** > **Start Up**: For all tests selected for start-up calibration a manual calibration request will be issued.

The set of tests that are calibrated in a start-up calibration, including the respective calibration methods, is defined on the **Start Up Setting** window.

► To select tests for start-up calibration

1 Choose **Calibration** > **Status** > **Start Up Setting**.

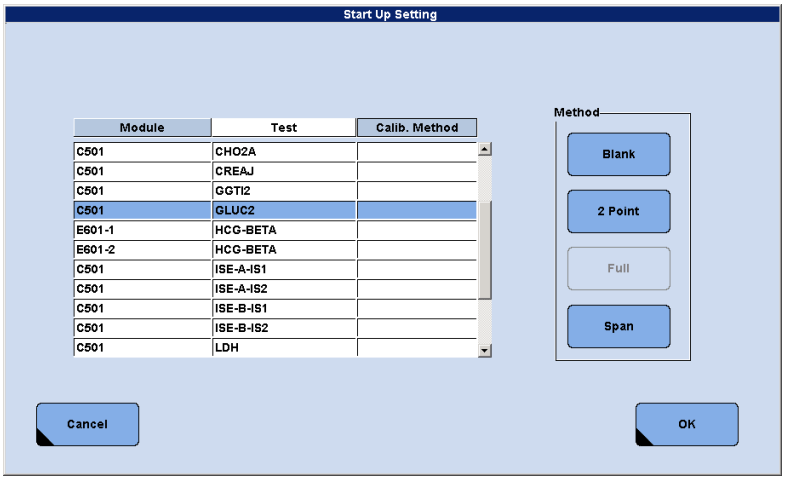


Figure B-89 Start Up Setting window

2 Choose a test in the list to select it.

3 Choose a method in the **Method** area to request it for the selected test. The **OK** button turns yellow indicating you have made a change.

- For **e** 601 tests, only **Full** is available as an option.
- For **c** 501 tests, for all non linear calibrations all methods are available. But according to the instructions for use, a full calibration must be performed.

4 Choose **OK** to save the start-up calibration settings and close the **Start Up Setting** window.

5 Choose **Start Up** on the **Calibration** > **Status** screen to activate the selected calibrations.

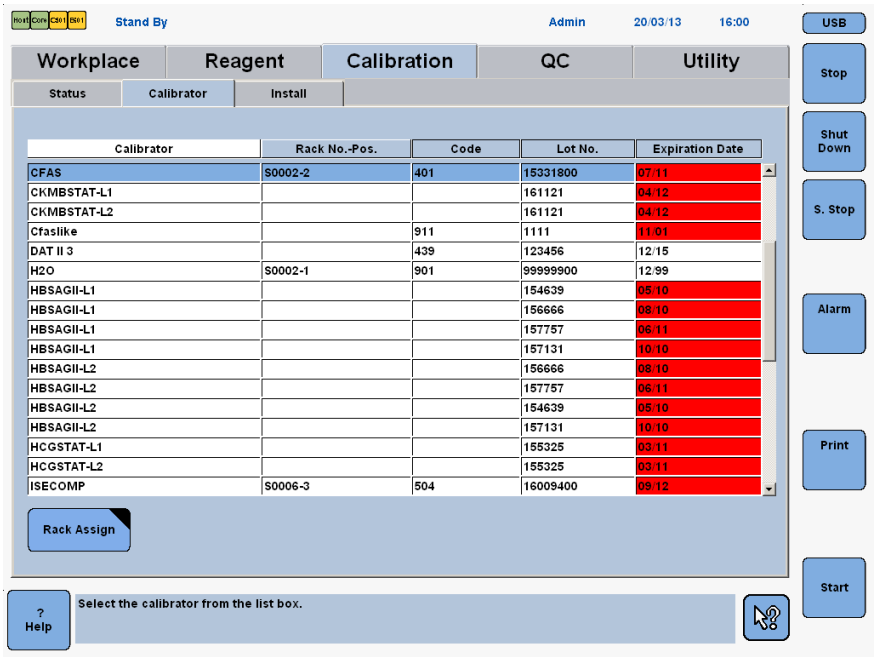
6 Choose **Save** to confirm the start-up calibrations.

■

Calibration Calibrator screen

The following sections explain certain tasks associated with the **Calibration** > **Calibrator** screen. Not all tasks are described, but the most important ones.

To display this screen choose **Calibration** > **Calibrator**.



Calibrator	Rack No.-Pos.	Code	Lot No.	Expiration Date
CFAS	S0002-2	401	15331800	07/11
CKMBSTAT-L1			161121	04/12
CKMBSTAT-L2			161121	04/12
Cfaslike		911	1111	11/01
DAT II 3		439	123456	12/15
H2O	S0002-1	901	99999900	12/99
HBSAGII-L1			154639	05/10
HBSAGII-L1			156666	08/10
HBSAGII-L1			157757	06/11
HBSAGII-L1			157131	10/10
HBSAGII-L2			156666	08/10
HBSAGII-L2			157757	06/11
HBSAGII-L2			154639	05/10
HBSAGII-L2			157131	10/10
HCGSTAT-L1			155325	03/11
HCGSTAT-L2			155325	03/11
ISECOMP	S0006-3	504	16009400	09/12

Figure B-90 Calibration > Calibrator window

The **Calibration** > **Calibrator** screen is used to review information about already registered calibrators and to assign calibrators to specific racks and positions. The rack assignment is necessary for calibrators that are used without barcode identification.

For information about particular tasks associated with this screen, see:
Assigning calibrator positions on page B-178
Loading calibrator vials for e 601 tests on page B-180

Assigning calibrator positions

Use the following procedure to assign a rack number and position to a calibrator if you are using cups without a barcode, or if the system cannot read the barcode on the calibrator vial.

Do not use barcoded calibrator vials on racks that have been assigned for non-barcoded calibrator vials.

- In this case the instrument generates an alarm and no calibration is performed. The rack is passed to the output buffer.
- If you have to manually assign a calibrator vial to a calibrator rack, for example, due to an unreadable barcode, place this calibrator vial on the assigned rack in the correct position.

► To assign calibrator positions

1 Choose **Calibration** > **Calibrator** > **Rack Assignment**.

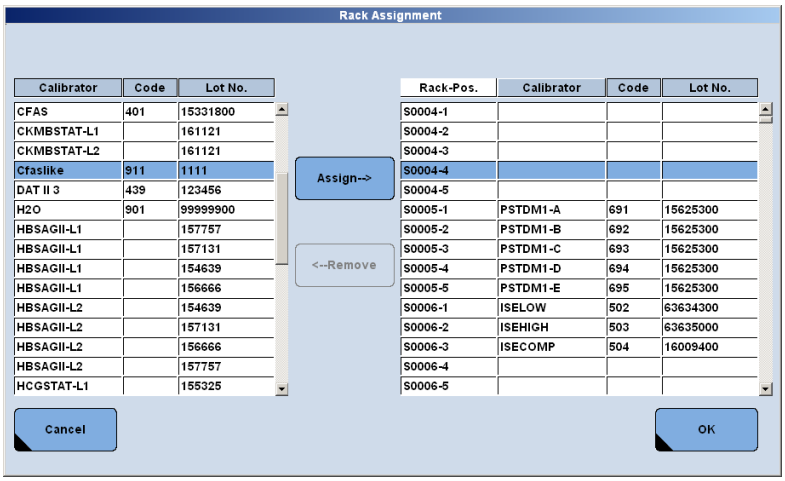


Figure B-91 Rack Assignment window

2 Select the calibrator to be assigned to a rack ID and position from the list on the left.

3 Select a rack ID and position from the list on the right:

- The position selected for the assignment has to be an empty line in the list.
- On **e** 601 modules the calibrator level 1 and level 2 must be assigned to consecutive positions on the same rack.
- On **c** 501 modules the calibrators can be on different racks.

Different designations for calibrator racks

There are following designations for the calibrator racks:

- Rack color: black
- Label on rack: C001 - C999
- Software displays: S00001 - S00999 or S0001 - S0999

4 Choose **Assign** to assign the selected calibrator to the selected position.

To undo the assignment choose **Remove** or choose **Cancel** to leave the **Rack Assignment** window without saving any changes.

5 To assign further calibrators repeat steps 2 to 4.

6 After all necessary assignments are completed, choose **OK** to save the changes.

■

Loading calibrator vials for e 601 tests

The calibrators used for the calibration of **e** 601 tests come in barcoded vials. To ensure correct pipetting from these vials it is important that they are placed correctly in the calibration racks.

- Before placing calibrators and controls on the loader, check that no bubbles or foam are visible on the liquid surface.
- Barcoded calibrator vials for **e** 601 modules can be used for a maximum of 4 calibration events.
- Calibrator vials of the same set are to be placed next to each other in the racks. Do not separate the vials of a calibration set.

► To load calibrator vials

1 Place both calibration vials of a CalSet in a black calibrator rack on consecutive positions. The order of Cal1 and Cal2 is not relevant. The picture shows an example.

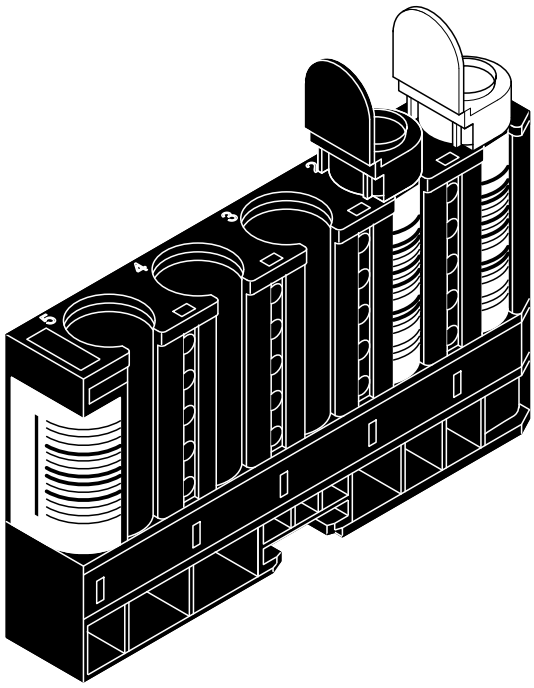


Figure B-92 Loaded vial on calibrator rack

2 Open the lid of the calibrator vials ensuring that they are on consecutive positions (see figure above).

3 Check the calibrator vials for foam and bubbles. Do not use calibrator vials containing foam or bubbles.

CAUTION! Injury due to contact with rack loader mechanism. Only load samples onto the rack loader when the green light on the rack loader is on.

4 Load the calibration rack into the loader.

■

Calibration Install screen

The following sections explain certain tasks associated with the **Calibration** > **Install** screen. Not all tasks are described, but the most important ones are discussed here.

To display this screen choose **Calibration** > **Install**.

If you want to update a calibrator of the **c** 501 module, choose the **Chemistry** tab.

If you want to update a calibrator of the **e** 601 module, choose the **Immune** tab.

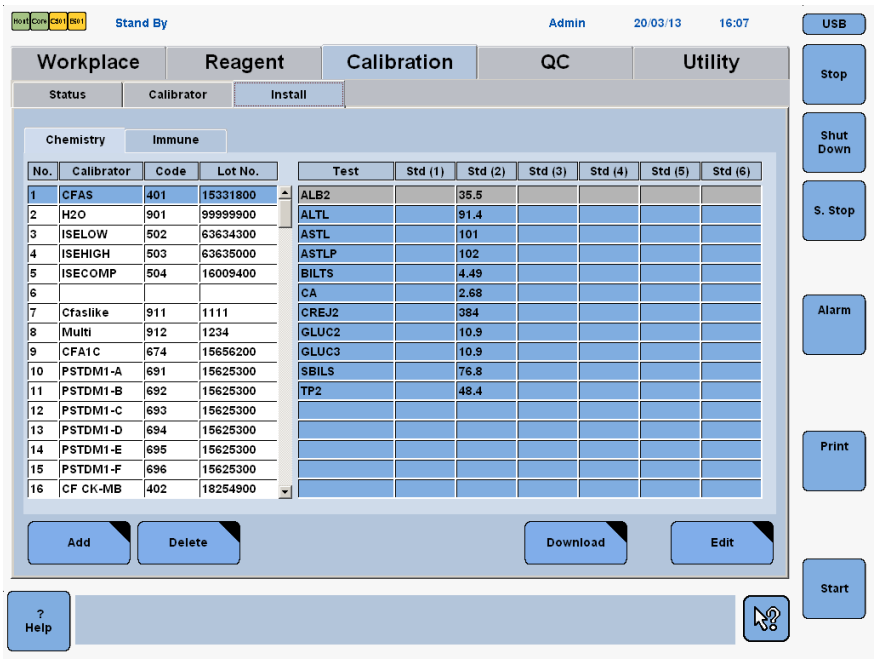


Figure B-93 Chemistry tab on Calibration > Install

The **Calibration** > **Install** screen is used to review information about already registered calibrators, to update calibrator information, and to install new calibrators.

For information about particular tasks associated with this screen, see:
Checking information about already installed calibrators on page B-182
Downloading or updating calibrator data on page B-184
Editing calibrator concentrations (c 501) on page B-189
Changing decimal places used for reportable data (c 501) on page B-191

Checking information about already installed calibrators

Information regarding calibrator codes, lot numbers, expiration dates, and calibrator concentrations can be downloaded to the system via **cobas** link.

This section describes how to check registered calibrator information.

► To check information on registered calibrators of the c 501 module

1 Choose **Calibration** > **Install** > **Chemistry**.

2 Select a calibrator from the list on the left.

The list on the left displays the following information:

- Calibrator name
- Calibrator code
- Lot number

The list on the right displays the following information:

- Test names
- Registered calibrator concentrations

👁 For detailed information on the **Calibration** > **Install** window, see *Install screen* on page E-300.

3 Choose **Calibration** > **Calibrator**.

The list displays the following information:

- Calibrator name
- Assigned rack number and position, if available
- Calibrator code
- Lot number
- Expiration date

👁 For detailed information on the **Calibration** > **Calibrator** window, see *Calibrator screen* on page E-296.

4 Choose **Utility** > **Application** > **Other**.

5 Select a **Test** in the test list.

The **Other** tab displays the following information:

- Calibrator codes of the assigned calibrators
- Normal sample volume for calibration (photometric test)
- Volume of diluent standard dispensed for calibrator (photometric test)
- Volume of diluent dispensed for dilution (photometric test)

👁 For detailed information on the **Utility** > **Application** > **Other** tab, see *Other (c 501 photometric tests)* on page E-512.

■

► To check information on registered calibrators of the e 601 module

1 Choose **Calibration** > **Install** > **Immune**.

The list on the left displays the following information:

- Calibrator name or the test name
- Lot number

The list on the right displays the following information:

Test name

For detailed information on the **Calibration** > **Install** window, see *Install screen* on page E-300.

2 Choose **Calibration** > **Calibrator**.

The list displays the following information:

- Test name and calibrator level
- Assigned rack number and position, if available
- Lot number
- Expiration date

Test name ?????

If **?????** is displayed as test name (**e** 601 calibrator), the corresponding application is either not installed or it is not assigned to a module or measurement cell.

For detailed information on the **Calibration** > **Calibrator** window, see *Calibrator screen* on page E-296.

3 To find the calibrator concentrations for the **e** 601 calibrators, choose **Calibration** > **Status**.

4 Select an **e** 601 test and choose **Calibration Result**. In the calibrator result table, the line **Target** displays the calibrator concentrations.

The calibrator concentrations are displayed only in this screen and only after the calibration is completed.

For detailed information on the **Calibration Result** window, see *Calibration Result (Immune) window* on page E-282.

■

Downloading or updating calibrator data

Information regarding calibrator codes, lot numbers, expiration dates, and calibrator concentrations can be downloaded to the system via **cobas** link. An operator with supervisor level or higher is required for this operation.

For instructions on entering calibration information manually, see *Editing calibrator concentrations (c 501)* on page B-189.

Downloading calibrator data is required in these situations:

- Installing an additional application

 During the installation of an application, the calibrator data for the corresponding test must be downloaded. If the new application is using a multi-analyte calibrator, the calibrator has to be re-downloaded to update the corresponding information.

- Using a new lot of a calibrator

 Calibrator data for a new lot must be downloaded. Calibrator settings, for example position assignment, are kept.

⚠ CAUTION

Incorrect results due to wrong calibration (c 501)

After changing the calibrator concentrations for any calibrator **Std (1)**-**Std (6)**, the calibration curve is immediately updated, even before the actual calibration measurement is performed.

For **Std (1)** this affects all calibration types, for **Std (2)**-**Std (6)** it affects all non-linear calibration methods (spline, line graph, RCM, RCM2T1 & RCM2T2). Therefore, in order to prevent incorrect results:

- Always recalibrate all affected tests included in the calibrator to obtain a lot calibration for the current reagent lot and for all previously registered reagents lots that will be used. In addition, all **cobas c** packs currently in use as well as temporally unloaded **cobas c** packs must be recalibrated.
- Make sure to perform the calibration measurement prior to any other determinations.

- Updating of calibrator data (**c** 501)

 Updating must be done when the calibrator concentrations of a downloaded calibrator are reassigned. If this occurs, the customers will be informed via an important note in the **cobas** e-library on **cobas** link.

 To update a calibrator the newest version of the calibrator data must be downloaded. The latest release date indicates the newest version.

 Calibrator settings, for example position assignment, are kept.

 ⚠ CAUTION

 Incorrect results due to wrong calibration (c 501)

 In order to prevent incorrect results, for all tests with reassigned calibrator concentrations a new lot calibration must be generated for the current lot and for all previously registered **cobas c** pack lots that will be used. In addition, all **cobas c** packs currently in use as well as temporally unloaded **cobas c** packs must be recalibrated.

 - Make sure to perform the calibration measurement prior to any other determinations.

For updating calibrator data, see *Download calibrator data* on page B-186.

No update of manually edited calibrator values (c 501)

In case a calibrator concentration has been manually edited, this calibrator concentration will not be updated when you download new calibrator data for an installed lot from **cobas** link. There is no indication in the software if the calibrator concentration was manually edited before.

- Check the calibrator concentrations after downloading.
- If you want to return to the original calibrator concentration, delete the calibrator and download it again from **cobas** link. Perform calibration before you resume routine operation.

No download necessary for inpack calibrators (e 601)

Calibrator data for inpack calibrators are read from the barcode of the **cobas e** pack. It is not possible to download calibrator data for inpack calibrators from **cobas** link.

See *Inpack calibrator* on page B-163.

Only one lot stored

Only one calibrator lot can be stored. Downloading a new calibrator lot overwrites the old calibrator lot. Calibrator settings, for example position assignment, are not overwritten.

For inpack calibrators (**e** 601), up to five lots can be stored.

See *Inpack calibrator* on page B-163.

Download calibrator data

How to download new or update existing calibrator data from **cobas** link is described in the following procedure.

⚠ CAUTION

Incorrect results due to wrong calibration (c 501)

After changing the calibrator concentrations for any calibrator **Std (1)**-**Std (6)**, the calibration curve is immediately updated, even before the actual calibration measurement is performed.

For **Std (1)** this affects all calibration types, for **Std (2)**-**Std (6)** it affects all non-linear calibration methods (spline, line graph, RCM, RCM2T1 & RCM2T2). Therefore, in order to prevent incorrect results:

- Always recalibrate all affected tests included in the calibrator to obtain a lot calibration for the current reagent lot and for all previously registered reagents lots that will be used. In addition, all **cobas c** packs currently in use as well as temporally unloaded **cobas c** packs must be recalibrated.
- Make sure to perform the calibration measurement prior to any other determinations.

No download for inpack calibrators (e 601)

Calibrator data for inpack calibrators are read from the barcode of the **cobas e** pack. It is not possible to download calibrator data for inpack calibrators from **cobas** link.

See *Inpack calibrator* on page B-163.

► To download calibrator data from cobas link

1 Put the analyzer in standby.

2 Choose **Calibration** > **Install** > **Download** to open the **Download** window.

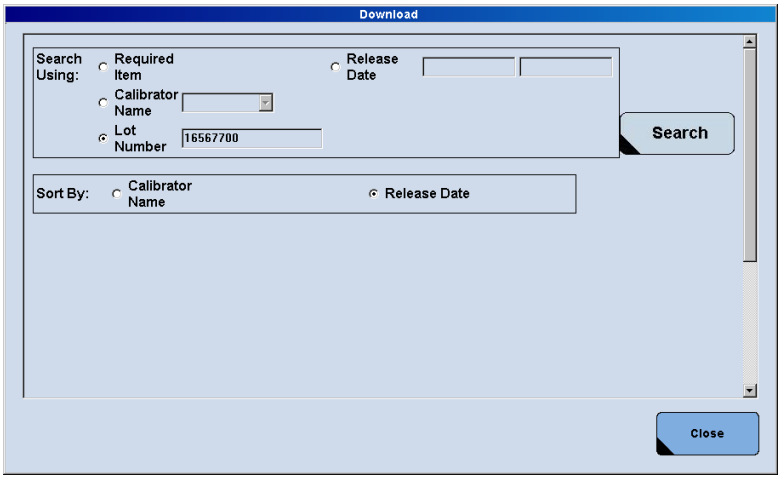


Figure B-94 Calibration download: Download window

3 Select one of the available search conditions (**Required Item**, **Calibrator Name**, **Lot Number**, or **Release Date**) in the **Search Using** area.

- **Lot Number** is the recommended search condition.

 Enter the first six digits of the lot number followed by two zeros.

- The option **Release Date** refers to the date when the calibrator was released by Roche Diagnostics.

4 Select **Release Date** in the **Sort By** area to sort the displayed search results by the release date.

5 Choose **Search**. A list of items that meet the given search conditions appears.

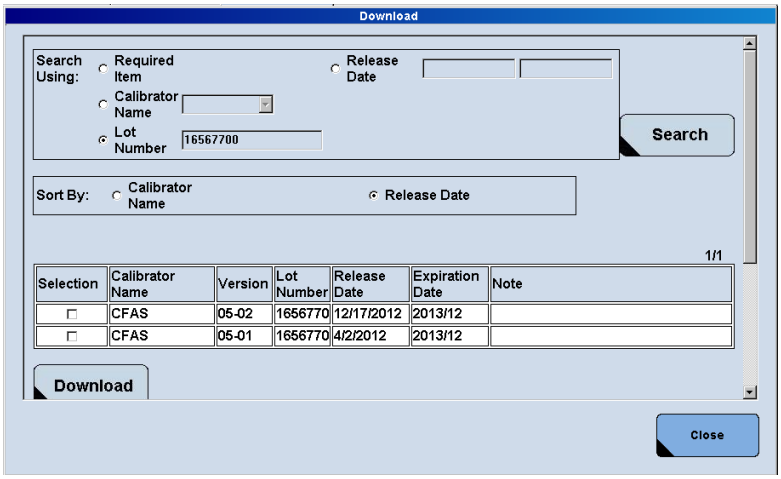


Figure B-95 Calibration download: Download window with search results

Several search results

If the **Download** window displays several search results, note the following:

- Choose **[Next >]** to display more search results.
- Use the scroll bar on the right side to display the **Download** button.

6 Select the check box of the list item to be downloaded.

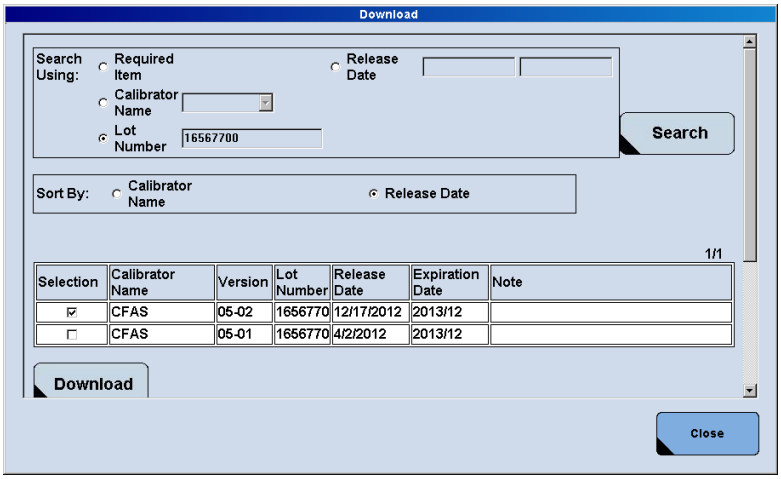


Figure B-96 Calibration download: Download window with selected item

Recommendation for download

If there are more calibrator entries for the same lot number, always download the calibrator data with the latest release date.

7 Choose **Download** and confirm with **OK**.

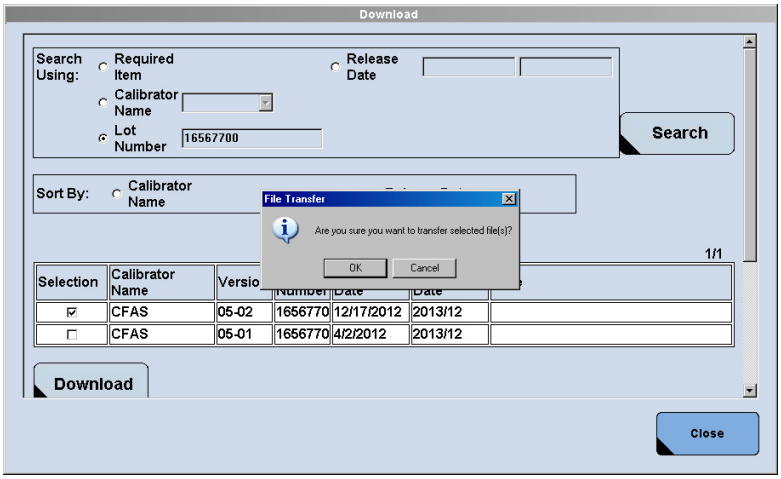


Figure B-97 Calibration download: Download and File Transfer window

8 Choose **OK** to confirm the **Confirmation** window.

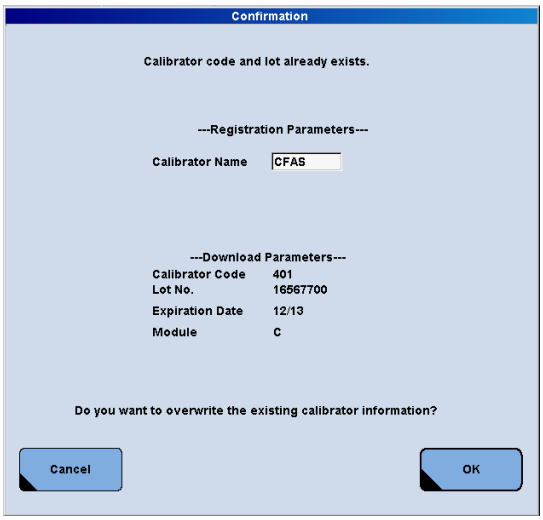


Figure B-98 Calibration download: Confirmation window

The **Confirmation** window displays the downloaded calibrator data. For **c** 501 calibrator you can edit the calibrator name.

9 Choose **Close** to return to the **Calibration** > **Install** screen and ensure the downloaded information has been registered correctly.

10 If needed, edit the decimal places for the calibrator data (**c** 501).

See *To edit decimal places used for reportable data (c 501)* on page B-192.

■

Editing calibrator concentrations (c 501)

The calibrator concentrations can be edited manually in the **Calibration** > **Install** > **Edit Calibrator** window (**c** 501 module only).

⚠ CAUTION

Incorrect results due to wrong calibration

After changing the calibrator concentrations for any calibrator **Std (1)**-**Std (6)**, the calibration curve is immediately updated, even before the actual calibration measurement is performed.

For **Std (1)** this affects all calibration types, for **Std (2)**-**Std (6)** it affects all non-linear calibration methods (spline, line graph, RCM, RCM2T1 & RCM2T2). Therefore, in order to prevent incorrect results:

- Always recalibrate all affected tests included in the calibrator to obtain a lot calibration for the current reagent lot and for all previously registered reagents lots that will be used. In addition, all **cobas c** packs currently in use as well as temporally unloaded **cobas c** packs must be recalibrated.
- Make sure to perform the calibration measurement prior to any other determinations.

No update of manually edited calibrator values (c 501)

In case a calibrator concentration has been manually edited, this calibrator concentration will not be updated when you download new calibrator data for an installed lot from **cobas** link. There is no indication in the software if the calibrator concentration was manually edited before.

- Check the calibrator concentrations after downloading.
- If you want to return to the original calibrator concentration, delete the calibrator and download it again from **cobas** link. Perform calibration before you resume routine operation.

► To edit calibrator concentrations (c 501)

1 Choose **Calibration** > **Install** > **Chemistry**.

2 Select the calibrator to be edited from the **Calibrator** list on the left.

3 Choose **Edit** to display the **Edit Calibrator** window.

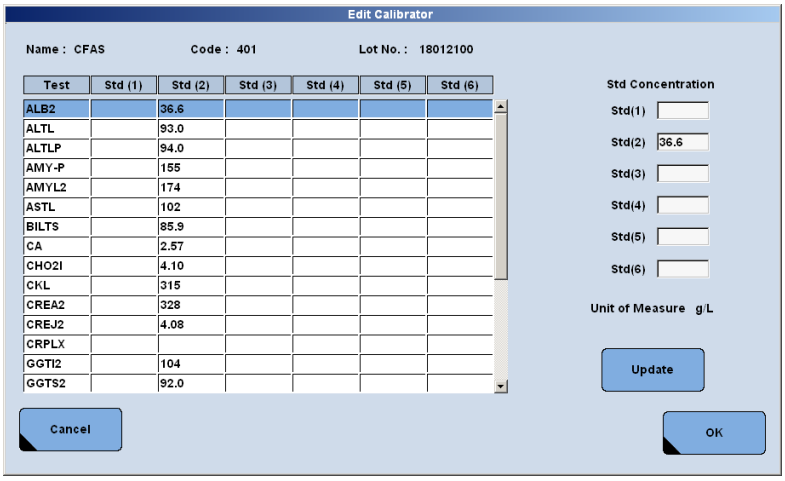


Figure B-99 Edit Calibrator window

4 Select a test from the **Test** list whose calibrator concentration is to be edited.

5 Select a text box in the **Std Concentration** area and type the appropriate concentration(s). Observe the respective **Unit of Measure** displayed below the **Std Concentration** area.

Std (1) is used for the blank calibrator. **Std (2)** through **Std (6)** are used for all other calibrators.

6 After all necessary calibrator concentrations are entered, complete the input by choosing **Update**.

7 If you need to edit additional tests, repeat steps 4 through 6.

8 Choose **OK** to save all changes.

9 Choose **Yes** to confirm the message of the confirmation window.

10 Calibrate all tests included in the edited calibrator to obtain a lot calibration for the current reagent lot and for all previously registered reagents lots that will be used.

Calibrate all **cobas c** packs currently in use and all temporally unloaded **cobas c** packs.

See *Requesting and cancelling calibrations manually* on page B-167.

■

Decimal places used for reportable data

The number of decimal places used for **Std (1)** defines the number of decimal places used for reportable data.

See *Changing decimal places used for reportable data (c 501)* on page B-191.

Changing decimal places used for reportable data (c 501)

The number of decimal places used for **Std (1)** defines the number of decimal places used for reportable data. It is recommended to edit the decimal places during the installation. However, it is possible to change the decimal places for installed tests.

⚠ CAUTION

Incorrect results due to wrong calibration

You can change the decimal places after an application has been installed. However, if the decimal places are changed after the test in question has already been calibrated, we strongly recommend deleting that test application and reinstalling it.

- After changing the decimal places always recalibrate and run controls in order to ensure no incorrect results are reported.

► To change the decimal places for an installed test (c 501)

1 Backup the database and delete patient data (**System Overview** > **Sample Data Clear** > **Backup and Clear**).

If sample data clear is executed, all the records of the samples are deleted and QC data are moved to the **QC View**.

👁 For details, see *Sample Data Clear button* on page B-44.

2 Unload all the **cobas c** packs for this test (**Reagent** > **Setting** > **Cassette Unloading**).

👁 For details, see *Unloading reagent cassettes* on page B-127.

3 Delete the test application (**Utility** > **Application > Delete**).

4 Reinstall the test application (**Utility** > **Application** > **Download**).

👁 For details, see *Installing an application* on page B-252.

5 Load new **cobas c** packs.

👁 For details, see *To load a cobas c pack* on page B-49.

6 Download the calibrator data for this test under **Calibration** > **Install** > **Download**.

👁 For details, see *Downloading or updating calibrator data* on page B-184.

7 Change the decimal places and calibrator concentrations (**Calibration** > **Install** > **Edit**).

👁 For details, see:
To edit decimal places used for reportable data (c 501) on page B-192
To edit calibrator concentrations (c 501) on page B-190

8 Download the control data for this test under **QC** > **Install** > **Download**.

👁 For details, see *Downloading control data* on page B-221.

9 Calibrate the test and perform control measurements.

👁 For details, see *Requesting calibration and QC and printing load lists* on page B-52.

■

cobas c pack unloaded to delete the application have to be discarded, since they will not be accepted by the **c** 501 module again.

► To edit decimal places used for reportable data (c 501)

1 Choose **Calibration** > **Install** > **Chemistry**.

2 Select the calibrator to be edited from the **Calibrator** list on the left.

3 Choose **Edit** to display the **Edit Calibrator** window.

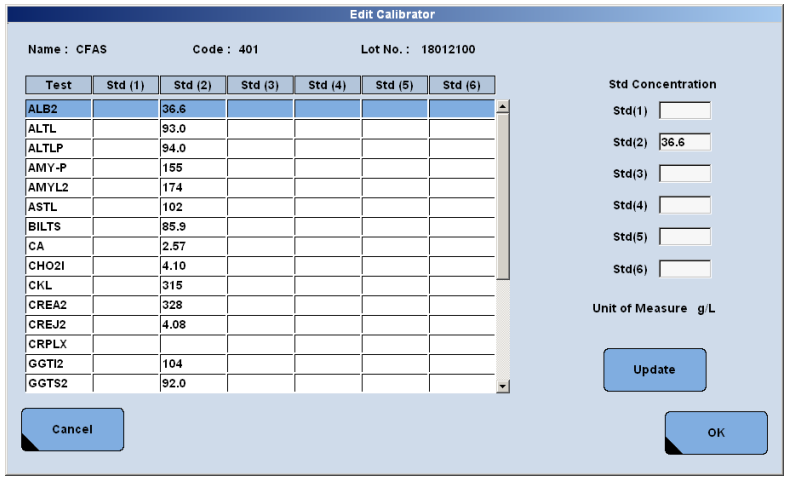


Figure B-100 Edit Calibrator window

4 Select a test from the **Test** list whose decimal places used for reportable data are to be edited.

5 Select the **Std (1)** text box in the **Std Concentration** area and add or delete decimal places.

The number of decimal places used for **Std (1)** defines the number of decimal places used for reportable data.

6 Choose **Update** to complete the input.

7 Choose **OK** to save all changes.

8 Choose **Yes** to confirm the message of the **Confirmation** window.

■

ISE calibration

ISE calibrators can be used with or without barcode. Therefore you have to download the calibrators, assign rack number and positions. Always use position 1, 2, and 3 for ISE Low, ISE High, and ISE High.

Even if your are using barcoded ISE calibrators you still have to assign the ISE calibrators to a rack. Run the barcoded ISE calibrators on a different calibration rack.

At installation of a new instrument, insert the calibrator code 502, 503 and 763 in the **Calibrator Code** text boxes on the **Utility** >**Application** > **Other** screen.

Do not use barcoded calibrators on racks that have been assigned for non-barcoded calibrators.

In this case the instrument generates an alarm and no calibration is performed. The rack is passed to the output buffer.

If the system configuration is done, use a (black) calibrator rack for the three calibrators used in an ISE calibration—ISE Low, ISE High, and ISE High—and put these in positions 1, 2, and 3 respectively according to the rack assignment.

For details, see *Editing calibrator concentrations (c 501)* on page B-189.

Sample type specific ISE calibration curves

For ISE tests it is possible to apply one of two independent calibration curves. After installation and assignment, the respective calibrator concentrations are displayed under **Type A** and **Type B** on **Utility** > **Application** > **Other**.

The assignment of one or the other calibration curve to a certain sample type is set on **Utility** > **System** (**Page 2/4**) > **ISE Calib Setting**.

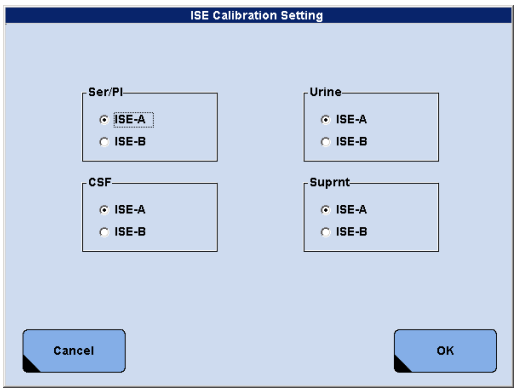


Figure B-101 Utility > System (Page 2/4) > ISE Calib Setting window

For more information, see *Setting up individual calibration curves for each ISE sample type* on page B-276.

System Overview screen

The following section explains calibration tasks associated with the **System Overview** screen.

Choose the graphical icon representing the configuration in the status line (top left of the screen), or press <F12> to display the **System Overview** screen.

Calibrating tests during operation

Calibration is usually performed at the beginning of routine operation before sample processing begins. However, it can be done anytime during routine operation as well.

The procedure for calibrating tests during operation is essentially the same as the calibration at the beginning of routine operation:

► To perform calibrations during operation

1. Request the recommended calibrations via the **Calibration and QC Selection** button (highlighted yellow) on the **System Overview** screen.
2. Print the **Load List**.
3. Prepare the calibrator(s).
4. Place the calibrator rack(s) on the loader.
5. Start the calibration measurement.

 👁 For detailed description of the calibration process at the beginning of routine operation, see *Calibration and QC Select button* on page B-51.

■

QC

This chapter provides descriptions of the basic QC concepts as well as of special tasks that are not usually part of the daily workflow. It is meant to complement the chapter Daily operation, where everyday tasks and common procedures for running the **cobas** 6000 analyzer series are described.

In this chapter

Chapter **12**

QC concept B-197
QC methods B-197
System implementations for QC measurements B-198
Accumulation methods for QC measurement data B-199
QC data base management B-200
Working in barcode or non-barcode mode B-201
Overview B-202
QC Status screen B-202
Timeout QC B-204
Requesting QC measurements B-205
QC after calibration B-206
QC Run Status screen B-207
QC Individual screen B-209
Excluding an individual QC point or adding a comment B-211
Configuring and using realtime QC B-212
Configuring realtime QC B-215
Accumulation of QC results B-215
System settings for QC accumulation B-216
Accumulating QC results B-216
QC Cumulative screen B-217
QC Control screen B-218
QC Install screen B-220
Downloading control data B-221
Editing control values B-224
Updating of control values B-225
Activating control tests B-227
Automatic QC measurement B-228
Configuring automatic QC measurement B-228
Unloading auto QC racks from the rack rotor B-229

QC concept

Regularly perform QC measurements to continually monitor the instrument performance. After measurement of QC samples, data can either be transferred to and evaluated on a Host or they can be evaluated on the system.

QC methods

The following QC methods are available on a **cobas** 6000 system: Individual (intra-day) QC, cumulative (long-term) QC, and realtime QC.

Individual and cumulative QC

All results of QC measurements can be viewed on the **QC** > **Run Status** screen and the **QC** > **Individual** screen. It is recommended to transfer QC data at the end of a day from the individual QC to the cumulative QC. Under cumulative QC you find all the long-term quality control information stored on the system.

For more information, see:
Accumulation methods for QC measurement data on page B-199
Accumulation of QC results on page B-215
QC Run Status screen on page B-207
QC Individual screen on page B-209
QC Cumulative screen on page B-217

Realtime QC

Independent of individual and cumulative QC, the realtime QC function allows the evaluation of QC measurement immediately after their results become available (realtime) utilizing the Westgard algorithm.

Realtime QC for one test always uses two kinds of controls and compares QC results against the controls' known standard deviation (SD) and mean values.

For more information on realtime QC, see *Configuring and using realtime QC* on page B-212.

System implementations for QC measurements

In addition to the QC *methods* explained above, there are six *types* of implementations which are available to manage the measurement of QC samples:

- Routine QC
- Stand by reagent QC
- Timeout QC
- Automatic QC
- QC after calibration
- Manual QC

Routine QC

Each test has one or more controls assigned to it. Moreover, a test must be not only *assigned* to a control but also *activated* for that control to make a QC measurement possible. Routine QC contains all activated tests of all installed controls. You can request a QC measurement for all of these tests—for example, at the beginning of a work shift—with one single command (**System Overview** > **Calibration and QC Select** > **Routine QC**).

For more information about routine QC, see:
Requesting QC measurements on page B-205
To perform controls for active reagents on page B-205

Stand by reagent QC

QC measurements can be requested individually for stand by reagents. Stand by reagents are **cobas c** packs and **cobas e** packs already on board but not in use at present.

For more information about stand by reagent QC, see:
Requesting QC measurements on page B-205
To perform controls for standby reagents on page B-206

Timeout QC

QC measurements can be performed at predefined (test-specific) time intervals. When the time interval has elapsed, the system issues a recommendation for a QC measurement. This is indicated by the **Calibration and QC Select** button on the **System Overview** screen lighting up in yellow. In case an automatic QC rack is in the auto QC position in the rack rotor, this rack is transferred to the sample line and measurements are performed fully automatically.

See *Timeout QC* on page B-204.

Automatic QC

It is possible to keep frequently used controls in the rack rotor—ready to be used any time before or during routine operation. Thus, in combination with Timeout QC, the system is able to perform QC measurements without any intervention by the operator.

See *Automatic QC measurement* on page B-228.

QC after calibration

For this kind of QC measurements no special settings are needed. Whenever a calibrator rack(s) (black rack) is immediately followed by a QC rack (white rack), QC measurements are performed for all calibrated tests without explicit requests from the operator if the corresponding test is activated for that control.

If you use *QC after calibration*, the QC results are always calculated with this new calibration curve.

For performing QC after calibration, see *QC after calibration* on page B-206.

Manual QC

This function allows to measure QCs of any activated test for the corresponding control whenever needed.

See *Requesting QC measurements* on page B-205.

Accumulation methods for QC measurement data

At the end of daily operation, QC measurement data should be accumulated. When accumulating QC results, the corresponding data are deleted from the **QC** > **Individual** screen and transferred to the **QC** > **Cumulative** screen.

Two accumulation methods

There are two accumulation methods available: **Mean-R** and **X-R**. The choice for one or the other method is made under **Utility** > **System** (**Page 1/4**) > **QC Setting**.

- **X-R** transfers only **one** QC result from individual QC to cumulative QC. Therefore you must specify a result when accumulating QC data.
- **Mean-R** calculates a mean of the data to be accumulated. This mean is then transferred to the cumulative QC data.

Two calculation methods

If **Mean-R** is set as accumulation method, two methods are available for the calculation of mean values and SD values in cumulative QC: **DayToDay** and **Overall**.

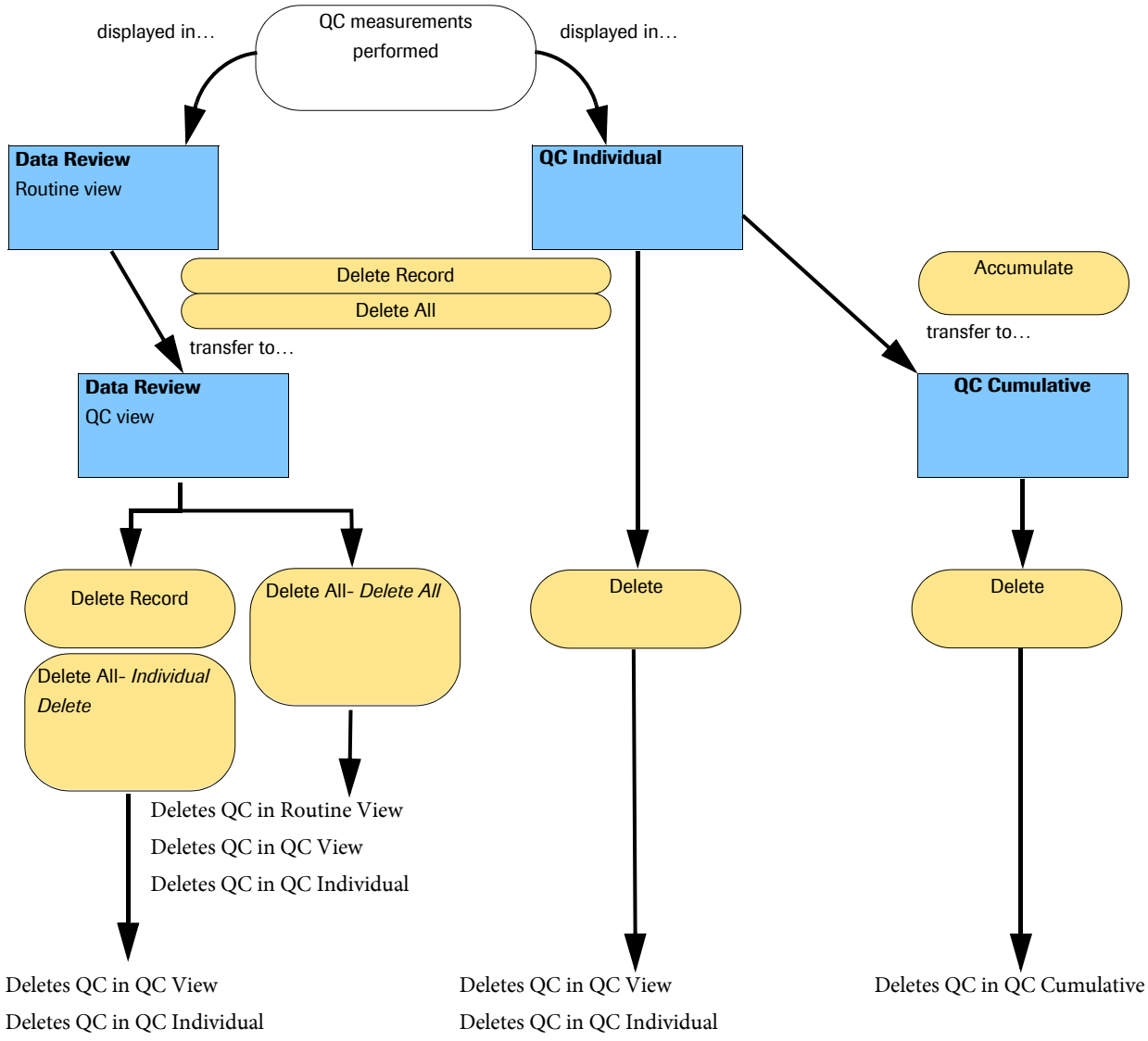
- The **Overall** method uses a weighting factor for each accumulated set of data.
- In the **DayToDay** calculation method all accumulations have the same weight.

The calculation method is selected under **Utility** > **System** (**Page 1/4**) > **QC Setting**.

For more information on the different calculations of mean and SD values according to the DayToDay or Overall method, see *Accumulation of QC results* on page B-215.

QC data base management

The following chart shows the handling of QC results starting with the measurement of QC samples and ending with the deletion of QC results. It shows the different screens that display QC results, and shows the particular action that moves (deletes, accumulates) the results from one screen to another screen.



Recommendation

Workflow for handling QC results in order to keep as little QC data as possible

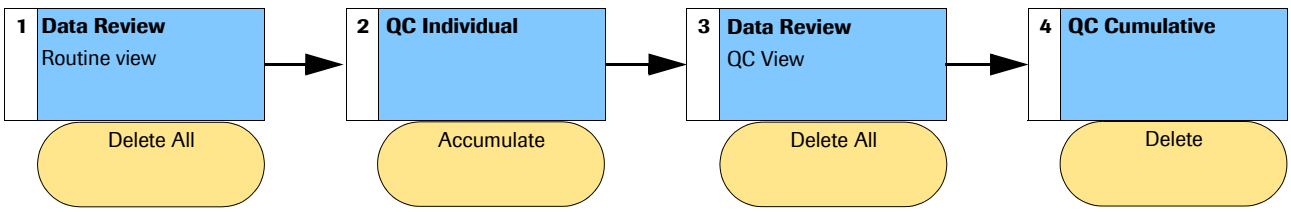


Figure B-102 Workflow for handling QC results

Summary **QC View** is linked with the QC individual database. If a QC result is deleted in the **QC View** database, it is as well deleted in the QC individual database and vice versa. Therefore it is recommended to first accumulate individual QC results before deleting QC data on **Data Review** > **QC View**.

QC data of the QC cumulative database should only be deleted, if the particular data is no longer required.

Deleting a control deletes all corresponding QC data

If you delete a control on the **QC** > **Install** screen, you also delete all corresponding QC data:

- QC > Individual
- QC > Cumulative
- QC > Run Status
- Workplace > Data Review > Routine View
- Workplace > Data Review > QC View

Working in barcode or non-barcode mode

On the **Utility** > **System** screen under **Barcode Setting**, you can verify or change whether the system uses barcodes for controls or not.

When working with barcodes, controls are automatically identified. In case controls are processed in non-barcode mode, it is necessary to assign a rack number and rack position for each control.

The current rack assignment is listed on the **QC** > **Control** screen. To provide additional assignments or remove existing assignments choose **Rack Assignment**.

- For assigned controls (without barcode), be sure to use the specified racks and positions. Misplacement would go undetected by the system and yield completely invalid results.
- Do not use barcoded controls on a QC rack that is assigned for non-barcoded controls.

For more information, see *QC Control screen* on page B-218.

Overview

The QC menu contains six screens: **QC** > **Status**, **QC** > **Run status**, and **QC** > **Individual, QC > Cumulative, QC > Control, QC > Install**. This chapter describes important commands accessed via these screens as well as various information displayed on them.

However, this chapter does not cover all possible commands. For a complete description of all fields of the software's user interface, refer to the *Online Help*.

For more information about the calibration menu, see Chapter 25 *Calibration menu*.

QC Status screen

The following sections explain certain tasks associated with the **QC** > **Status** screen. Not all tasks are described, but the most important ones are discussed here.

To display this screen choose **QC** > **Status**.

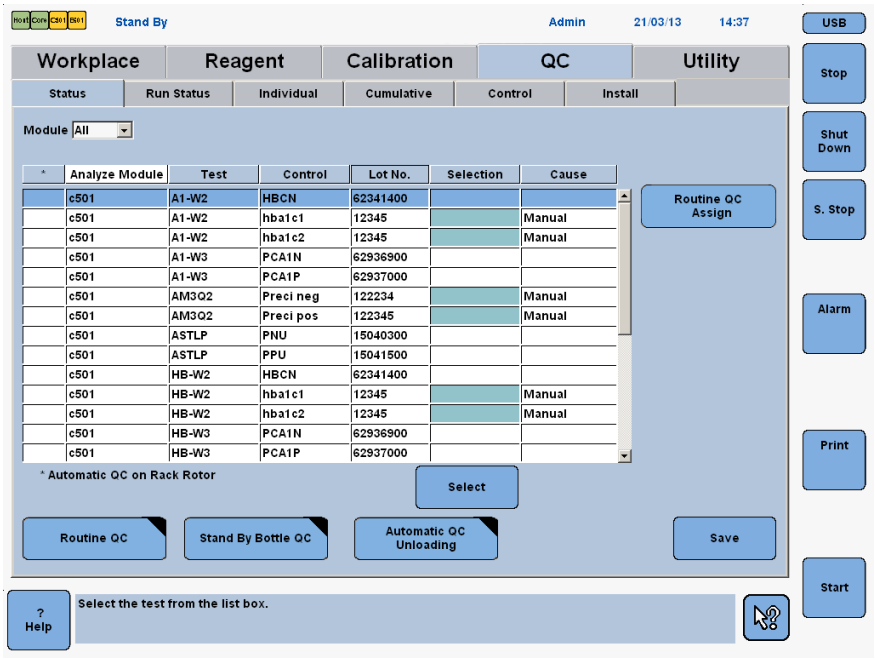


Figure B-103 QC > Status screen

The **QC** > **Status** screen displays all installed controls with the corresponding assigned and activated tests for each module and measuring cell.

The test display can be sorted by module, test name (alphabetical order), control name (alphabetical order), QC test selection, or QC cause. Tests can be selected with the **Select/Deselect** button. Selected tests are highlighted in green. A control test selection is made for the subsequent control run. The control test selections of the status list are reset after the control is measured.



Only the test selection of pipetted control tests are reset. If a test is requested but the control vial is not inserted, the QC request remains.

An asterisk (*) in the first column of the **QC** > **Status** screen denotes which control is used as automatic QC.

For more information, see *Automatic QC measurement* on page B-228.

Routine QC Assign

The **Routine QC Assign** button selects all Routine QC tests (current reagents only) for a control measurement. Routine QC tests are all activated tests for all installed controls. Tests that are not to be measured can be deselected on the **Status** screen: Highlight the concerned line(s) on the status list and then use the green **Deselect** button.

For more information, see *To perform controls for active reagents* on page B-205.

Direct access from System Overview screen

From the **System Overview** screen, select the **Calibration and QC Select** button and then the **Routine QC** button in the **QC** area on the right. This is the same as selecting the **Routine QC Assign** button on **QC** > **Status**.

For more information, see *To request calibration and QC* on page B-53.

Automatic QC Unloading

Use this button to unload auto QC racks from the rack rotor. In the **Automatic QC Unloading** window select the rack(s) to be unloaded and choose **Select**. Then choose **Execute**.

For more information, see *Automatic QC measurement* on page B-228.

Timeout QC

A control interval in hours can be defined for each application on the **Range** tab on **Utility** > **Application**. Select the **Control Interval Time** check box and type the appropriate time in the adjacent text box.

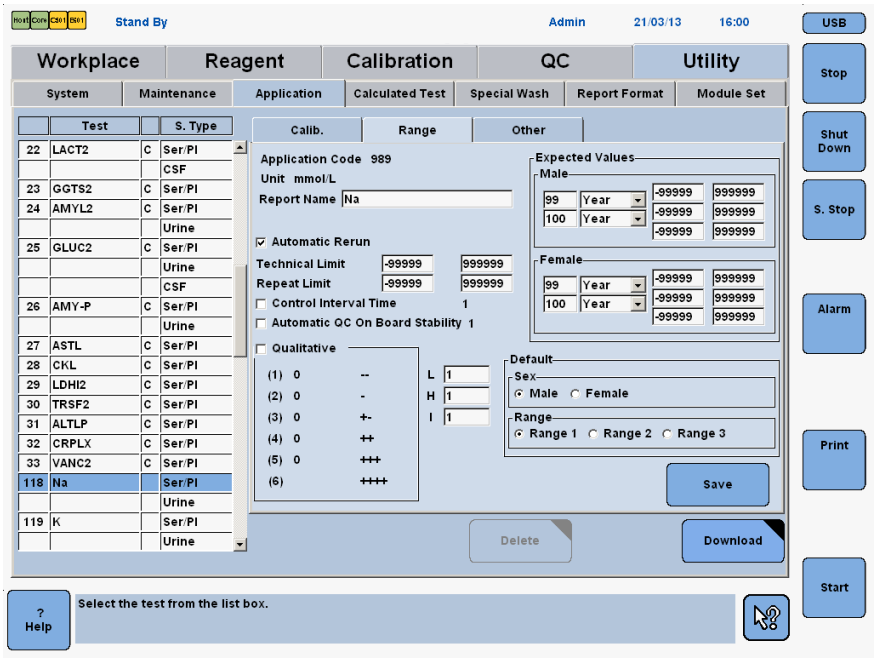


Figure B-104 Range tab on Utility > Application

The system checks the timeout every 30 minutes. When the specified time has elapsed, a QC request is triggered. This QC request is indicated on the **QC** > **Status** screen by the word *Timeout* in the **Cause** column.

If there is an auto QC rack in the rack rotor with a suitable control, the system performs an automatic QC.

The control is measured with the active (in use) **cobas c** pack or **cobas e** pack.

Requesting QC measurements

QC measurements can be requested individually for active and standby reagents. Active reagents are **cobas c** packs and **cobas e** packs currently in use. Standby reagents are **cobas c** packs and **cobas e** packs already on board but not in use at present.

- Do not use expired controls on **c** 501 and **e** 601 modules. The instrument issues no alarm when using expired controls.

Whether controls are expired can be checked in *QC Control screen* on page B-218.

- Do not use barcoded control vials on the same rack as assigned for non-barcoded control vials.

For more information about requesting QC manually, see:
Requesting calibration and QC and printing load lists on page B-52
To perform controls for active reagents on page B-205
To perform controls for standby reagents on page B-206
QC after calibration on page B-206

► To perform controls for active reagents

1 On **QC** > **Status** select the module where the QC is to be performed from the **Module** box.

2 If routine QC is to be performed, choose **Routine QC** to select all tests that are currently loaded on the system and activated for QC.

If individual tests are to be selected, go to step 3.

3 Choose the appropriate test, control and measuring channel, if applicable. Multiple tests, controls and measuring channels can be highlighted.

4 Choose **Select**. A green bar appears in the **Selection** column. **Manual** is displayed in the **Cause** column.

The **Select** button toggles to **Deselect**.

5 Choose **Save** to request the selected controls for measurement.

6 **Print** a **QC Load List** and load controls onto the system.

- Choose **Print** (global button) > **QC** and select **QC Load List**.
- Choose **Print**. The System prints a **QC Load List**.

CAUTION! Injury due to contact with rack loader mechanism. Only load controls onto the rack loader when the green light on the rack loader is on.

- Place the controls in white racks and load them onto the loader.

You can also print a **QC Load List** from **System Overview** > **Calibration and QC Select**. Select the **QC Only** option in the **Load List** area and choose **Print**.

■

Routine QC does not include QC measurement for standby reagents. To perform controls for standby reagents, QC measurement has to be requested separately.

► To perform controls for standby reagents

- **Stand By Bottle QC** can only be requested in **Stand By**, **Rack Supply Complete**, or **Rack Collect End**.
- Additional steps may be necessary if your **cobas** 6000 system is connected to a preanalytical system.

1 On **QC** > **Status** choose **Stand By Bottle QC** to display the **Stand By Bottle QC** window.

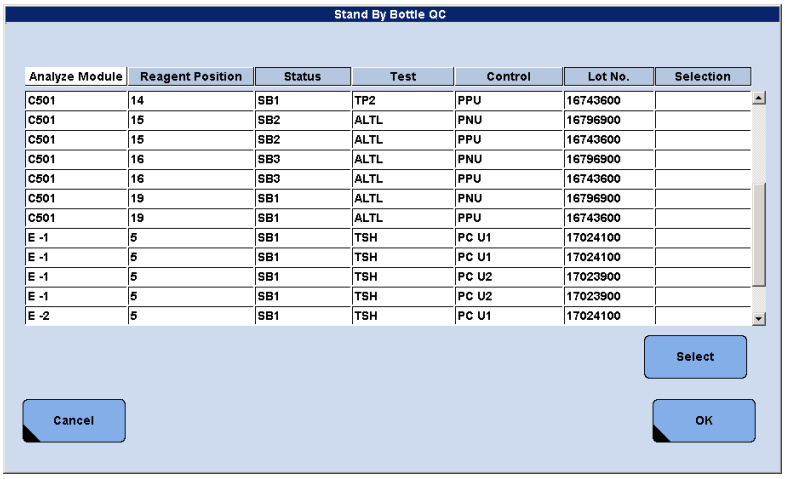


Figure B-105 Stand By Bottle QC window

2 Select the appropriate test, control, and measuring channel if applicable. Multiple tests, controls, and measuring channels can be highlighted.

3 Choose **Select**. A green bar appears in the **Selection** column.

The **Select** button toggles to **Deselect**.

4 Choose **OK** to request the selected controls for measurement.

5 Print a **QC Load List** and load controls onto the system.

■

QC after calibration

A calibration request automatically triggers a QC request for that reagent (current and standby reagents). A QC rack has to directly follow the calibrator rack.

If you are using calibrators on more than one rack, place all calibrator racks before the QC racks.

For more information about QC after calibration, see *QC after calibration* on page B-199.

QC Run Status screen

To display this screen choose **QC** > **Run Status.**

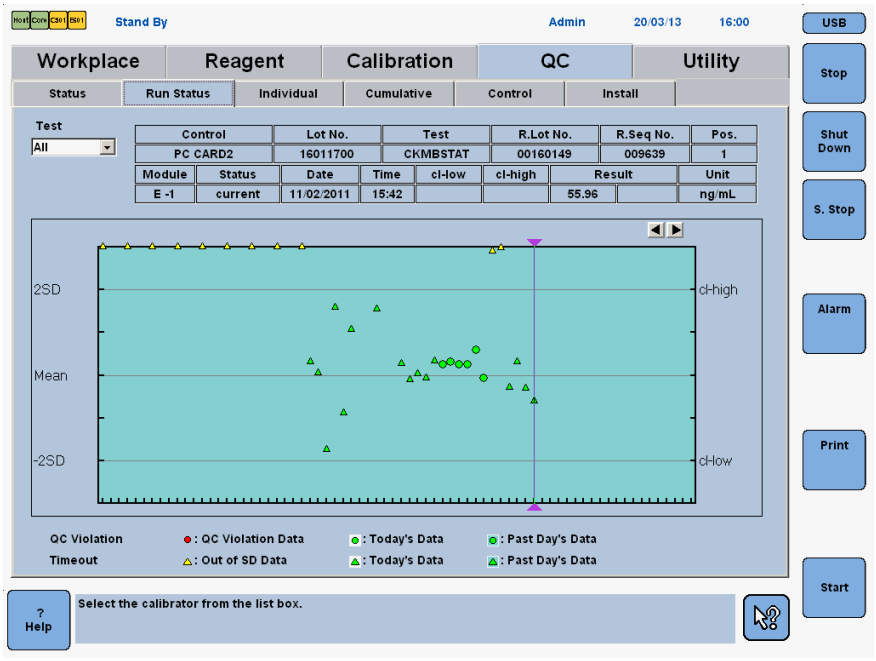


Figure B-106 QC > Run Status screen

Use the **Run Status** screen to get an overview of the last 500 quality control (QC) measurements performed on the analyzer or to view the most recent QC measurements for one particular test.

Use the **Test** box to select all tests or one specific test to be displayed on the chart. Use the arrows at the top right of the chart to move the focus from one result to the next.

QC run status details

The **Run Status** screen consists of a details area in the upper part of the screen and a run status chart in the center of the screen. The details area displays information that relates to the QC measurement selected on the run status chart. The chart in the center of the **Run Status** screen displays up to 500 results of QC measurements.

Chart background

A white background refers to today's measurements. A green background refers to past days' measurements.

Chart symbols

Shape: Circles are used when **QC Violation** is activated; otherwise triangles are used.

For more information on **QC Violation**, see *QC-triggered calibration (QC Violation)* on page B-157.

Color: Red and yellow denote a QC result falls out of confidence limits or 2 SD limits, respectively. Green symbols are used for results within the relevant limits.

	Displayed if QC violation is activated	QC result exceeds confidence limit (right axis of chart). A calibration is automatically recommended for the affected test.
	Displayed if QC violation is activated	QC result within confidence limits
	Displayed if QC violation is not activated and confidence limits are not checked	QC result falls outside ± 2 SD (left axis of chart)
	Displayed if QC violation is not activated	QC result within ± 2 SD

Special fields in the details area

Status: This field displays a reagent's status of precedence. Possible values are **Current**, **SB1**, **SB2**, **SB3**…

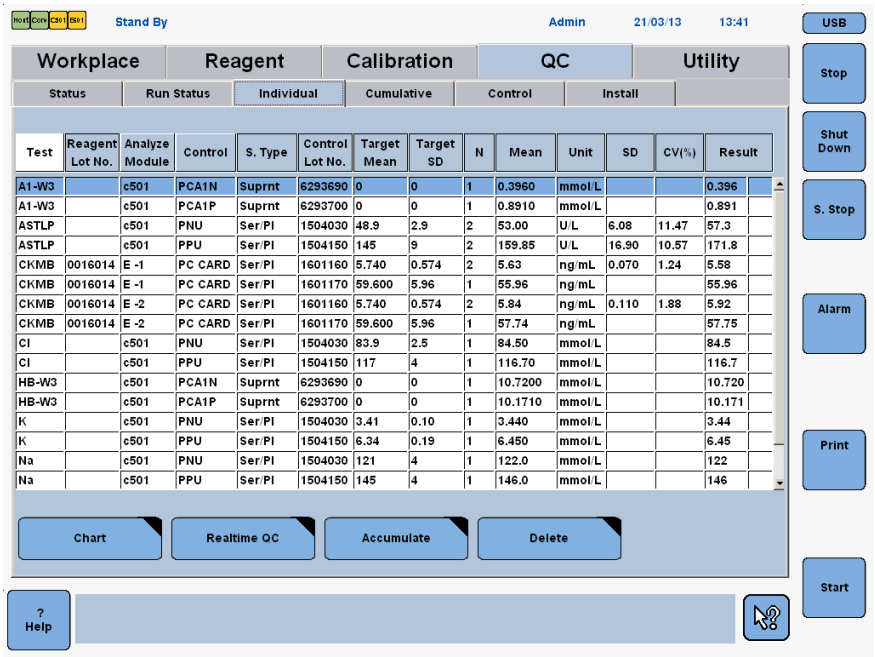
Current	Reagent (that is, **cobas c** pack or **cobas e** pack) currently in use
SB1	(Standby reagent 1) The reagent which will be used after the current reagent
SB2	(Standby reagent 2) The reagent which will be used after SB1 reagent

cl-low / cl-high: These fields display the confidence limits specified for the selected test. If the selected test is not configured for QC violation but for timeout calibration, the fields under **cl-low** and **cl-high** are blank.

QC Individual screen

The following sections explain certain tasks associated with the **QC** > **Individual** screen. Not all tasks are described, but the most important ones are discussed here.

To display this screen choose **QC** > **Individual.**



Test	Reagent Lot No.	Analyze Module	Control	S. Type	Control Lot No.	Target Mean	Target SD	N	Mean	Unit	SD	CV(%)	Result
A1-W3		c501	PCA1N	Suprnt	6293690	0	0	1	0.3960	mmol/L			0.396
A1-W3		c501	PCA1P	Suprnt	6293700	0	0	1	0.8910	mmol/L			0.891
ASTLP		c501	PNU	Ser/Pl	1504030	48.9	2.9	2	53.00	U/L	6.08	11.47	57.3
ASTLP		c501	PPU	Ser/Pl	1504150	145	9	2	159.85	U/L	16.90	10.57	171.8
CKMB	0016014	E -1	PC CARD	Ser/Pl	1601160	5.740	0.574	2	5.63	ng/mL	0.070	1.24	5.58
CKMB	0016014	E -1	PC CARD	Ser/Pl	1601170	59.600	5.96	1	55.96	ng/mL			55.96
CKMB	0016014	E -2	PC CARD	Ser/Pl	1601160	5.740	0.574	2	5.84	ng/mL	0.110	1.88	5.92
CKMB	0016014	E -2	PC CARD	Ser/Pl	1601170	59.600	5.96	1	57.74	ng/mL			57.75
Cl		c501	PNU	Ser/Pl	1504030	83.9	2.5	1	84.50	mmol/L			84.5
Cl		c501	PPU	Ser/Pl	1504150	117	4	1	116.70	mmol/L			116.7
HB-W3		c501	PCA1N	Suprnt	6293690	0	0	1	10.7200	mmol/L			10.720
HB-W3		c501	PCA1P	Suprnt	6293700	0	0	1	10.1710	mmol/L			10.171
K		c501	PNU	Ser/Pl	1504030	3.41	0.10	1	3.440	mmol/L			3.44
K		c501	PPU	Ser/Pl	1504150	6.34	0.19	1	6.450	mmol/L			6.45
Na		c501	PNU	Ser/Pl	1504030	121	4	1	122.0	mmol/L			122
Na		c501	PPU	Ser/Pl	1504150	145	4	1	146.0	mmol/L			146

Figure B-107 QC > Individual screen

The **QC** > **Individual** screen lists all non-accumulated QC results.

The list can be sorted by test name, module, and control name. The table below explains the most important columns of the list.

Reagent Lot No.	**cobas e** pack number (for **e** 601)
Control	Name of the control
Control Lot No.	Lot number of control material
Target Mean	Control target mean
Target SD	Control target standard deviation
N	Number of QC runs carried out on this control since the last accumulation
Mean	Calculated mean of N measurement results
SD	Standard deviation calculated from N control measurements
CV [%]	Coefficient of variation calculated from the mean value
Result	Most recent QC result of this control

For information about particular tasks associated with this screen, see *Excluding an individual QC point or adding a comment* on page B-211.

On the **QC** > **Individual** screen, choose **Chart** to open the **Individual QC Chart** window.

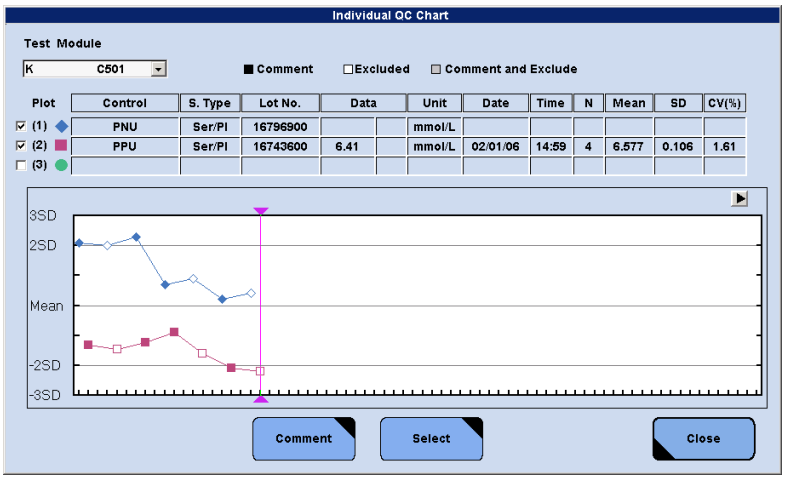


Figure B-108 Individual QC Chart window

This window displays all non-accumulated QC results for the selected test in a Levey-Jennings chart. A Levey-Jennings chart provides a visual method of monitoring trends in QC results. The result values are scaled to the standard deviation (SD) of the respective test.

Up to three controls for one test can be selected (**Select** button) and displayed on one chart.

If for one test different sample types are defined (**S. Type**), for example serum and urine, then the corresponding control within the QC chart must be selected, based on the sample type.

Excluding an individual QC point or adding a comment

Individual QC points on a QC chart can be excluded from QC calculations if required. It is also possible to annotate individual QC points.

► To exclude an individual QC point and add a comment

1 Choose **QC** > **Individual** > **Chart**.

2 Select the QC point to be excluded from QC calculations.

3 Choose **Comment** on the **Individual QC Chart** window to display the **Comment** window.

4 If necessary type a comment (max. 20 characters) in the **Comment** box.

5 Choose **Exclude**. The window is closed after confirmation.

This removes the point from statistics but continues to display the information on the chart.

■	A comment is attached to this point
□	This point is excluded Also results from a standby **cobas c** pack/**cobas e** pack are shown as excluded without a comment.
■	This point is excluded and a comment is attached

Excluded points cannot be included later.

6 Choose **OK**.

■

Configuring and using realtime QC

In realtime QC the system uses the Westgard algorithm to evaluate QC measurements. The Westgard algorithm is based on a multi-rule Shewhart-type method and applies a set of rules to each QC. These rules are selected from **QC** > **Individual** > **Realtime QC** > **Select Rules** for each test.

Quality control by the Shewhart method

The instrument measures two control samples (X and Y) in pairs, whose mean value ($\bar{X}$) and standard deviation (SD) are known for each test. Each QC result is processed according to the judgment standard (multi-rule) and it is judged whether it can be reported or not.—When the algorithm yields an error, an alarm is generated indicating whether the error is random error, QC error, or systematic error.

The kinds of realtime QC samples are 100 at a maximum. Figure B-109 shows an illustration of the multi-rule chart.

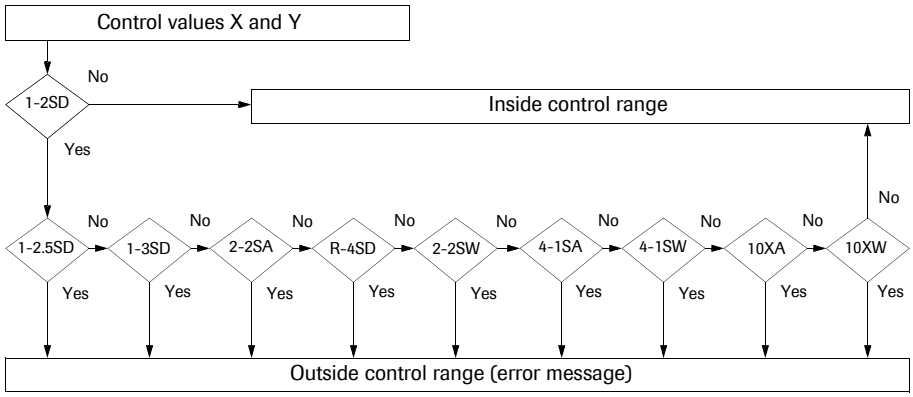


Figure B-109 Application of multi-rule Shewhart-type method in realtime QC

Configuration of realtime QC

Configure realtime QC in **Realtime QC** window (**QC** > **Individual** > **Realtime QC**): Choose **Select** to specify control (X) and control (Y) for each relevant test. Then, choose **Rules** to select the rules.

Only QC results of currently used **cobas c** packs and **cobas e** packs are evaluated.

For more details see *Configuring realtime QC* on page B-215.

The following table briefly explains all rules that are selectable for realtime QC and lists the corresponding alarms.

For more details, refer to the *COBI-CD*.

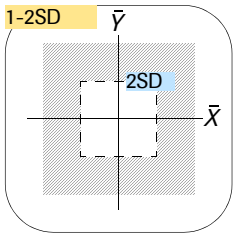
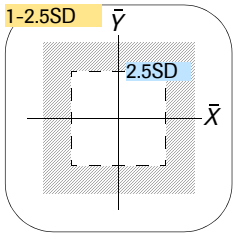
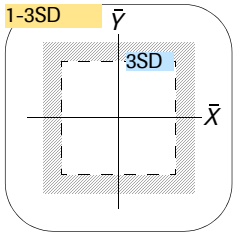
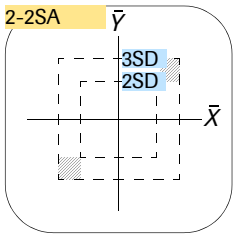
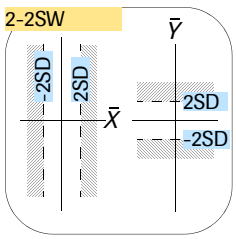
Rule	Order	Judgement	Judgment area	Alarm
1-2SD	1	Either X or Y data value is above +2SD or below -2SD.		None
1-2.5SD	2	Either X or Y data value is above +2.5SD or below -2.5SD.		Q2.5SD
1-3SD	3	Either X or Y data value is above +3SD or below -3SD.		Q3SD
2-2SD	4	Both of X and Y data values are above +2SD or below -2SD.		S2-2Sa
	6	The last two X or Y data values are above +2SD or below -2SD.		S2-2Sw

Table B-28 QC evaluation by Shewhart multi-rule method and corresponding alarms (Sheet 1 of 2)

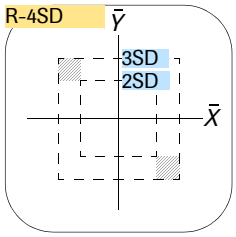
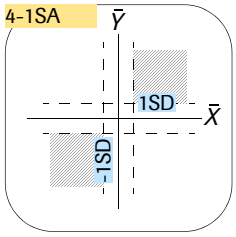
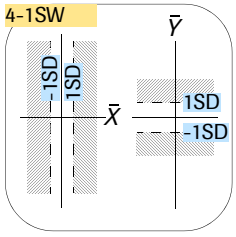
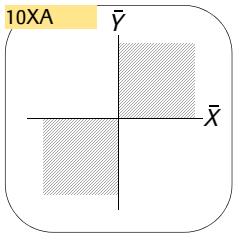
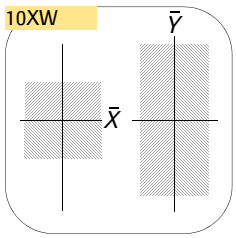
Rule	Order	Judgement	Judgment area	Alarm
R-4SD	5	One of X and Y data value is above +2SD and the other is below -2SD.		R-4SD
4-1SD	7	The last two X and Y data values are above +1SD or below -1SD. (Total 4 values)		S4-1Sa
	8	The last four X or Y data values are above +1SD or below -1SD.		S4-1Sw
10X	9	The last five X and Y data values fall on the + or - side of the mean value. (Total 10 values)		S10Xa
	10	The last ten X or Y data values fall on the + or - side of the mean value.		S10Xw

Table B-28 QC evaluation by Shewhart multi-rule method and corresponding alarms (Sheet 2 of 2)

Configuring realtime QC

Choose **QC** > **Individual** > **Realtime QC** to display the **Realtime QC** window.

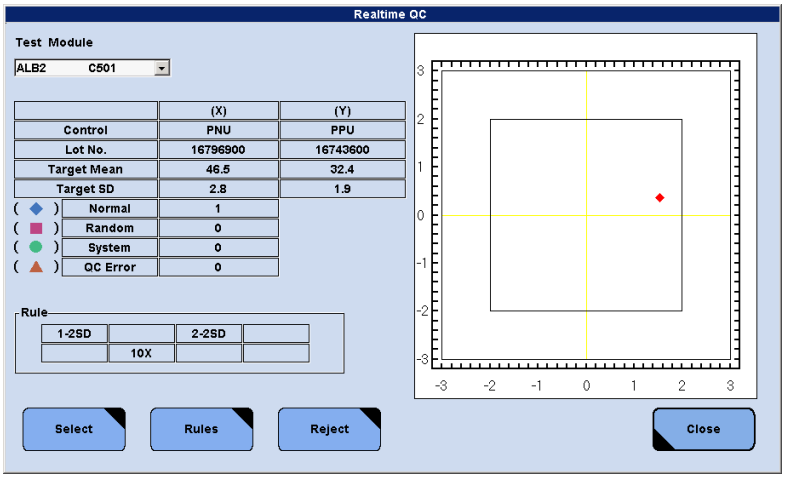


Figure B-110 Realtime QC window

This window shows a diagram with the QC results for a selected test and a selected pair of controls. The diagram is scaled to the target SD of control (X) and control (Y), respectively. The newest QC result is shown in red.

Select Choose this button to assign two controls—control (X) and control (Y)— to be evaluated by the multi-rule method.

Rules Choose this button to select rules used to evaluate the QC results. A pair of controls is compared against a known standard deviation (SD) and mean. If one or both of the controls fail a rule, the system continues applying the testing criteria for all selected rules. When at least one rule violation is found, the corresponding data alarm is issued.

The following symbols are used in the realtime QC plot:

- Normal: Without QC errors
- Random: Random QC errors
- System: System QC errors
- With intermediate QC errors

Reject Choose this button to reject realtime QC results that have specific data alarms attached. Affected result points are removed from the plot.

Accumulation of QC results

At the end of daily operation, QC measurement data should be accumulated. There are two accumulation methods available: **Mean-R** and **X-R**. The choice for one or the other method is made under **Utility** > **System** (**Page 1/4**) > **QC Setting**.

For an explanation of the two accumulation methods, see *Accumulation methods for QC measurement data* on page B-199.

System settings for QC accumulation

Choose **Utility** > **System** (**Page 1/4**) > **QC Setting** to display the **QC Setting** window.

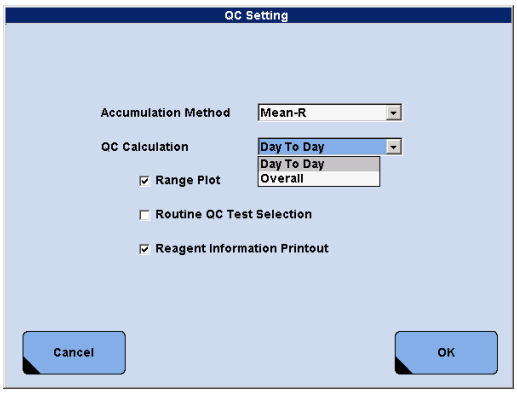


Figure B-111 Utility > System (Page 1/4) > QC Setting window

Accumulation Method Select one of the two accumulation methods, **Mean**-**R** or **X**-**R**, from this box.

See *Accumulation methods for QC measurement data* on page B-199.

QC Calculation If the accumulation method is **Mean**-**R**, select one of the two calculation methods, **DayToDay** or **Overall**, from this box to specify how mean and SD values are calculated in the cumulative QC.

This box is not available if **X**-**R** is selected in the **Accumulation Method** box.

For more information on system settings, see *System configuration* on page B-277.

Accumulating QC results

This section describes how to accumulate the QC data.

► To accumulate QC data

1. Select the data to be accumulated from the list on the **QC** > **Individual** screen.
2. Choose **Accumulate**.
3. If **Mean**-**R** is set as accumulation method, go to step 4.

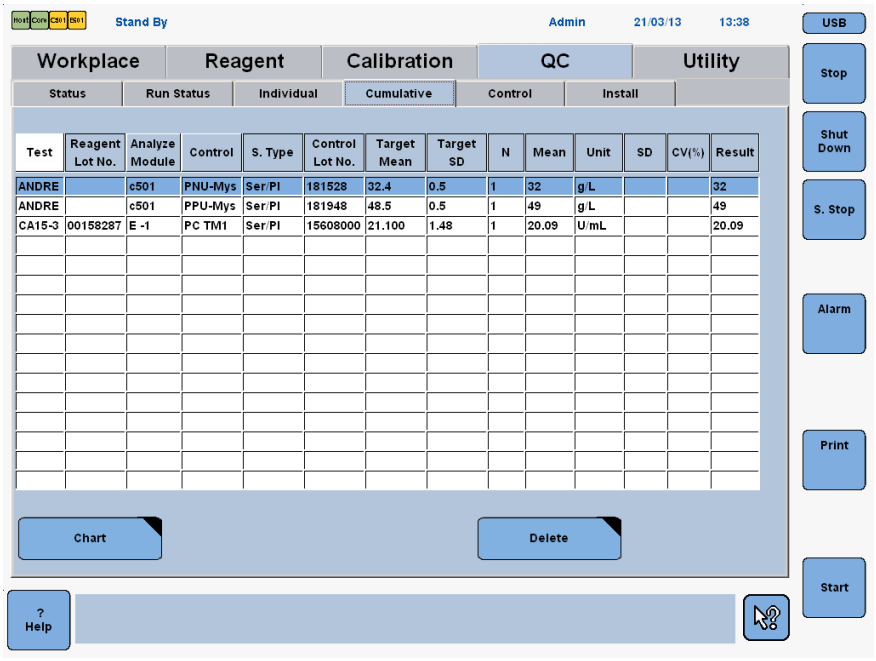
 If **X**-**R** is set as accumulation method, type the consecutive number of the QC result to be used for the accumulation in the box or type 0 (zero) to transfer the mean value; then choose **OK**.
4. In the confirmation window choose **Yes** to accumulate the selected data.

 After accumulation the corresponding data are deleted from the **QC** > **Individual** screen and a new standard deviation (SD) and mean value is calculated and displayed on **QC** > **Cumulative**. But if later new QC data with this control is generated, the accumulated results will be displayed again in the QC chart with the indication that they are already accumulated.

■

QC Cumulative screen

To display this screen choose **QC** > **Cumulative.**



Test	Reagent Lot No.	Analyze Module	Control	S. Type	Control Lot No.	Target Mean	Target SD	N	Mean	Unit	SD	CV(%)	Result
ANDRE		c501	PNU-Mys	Ser/Pl	181528	32.4	0.5	1	32	g/L			32
ANDRE		c501	PPU-Mys	Ser/Pl	181948	48.5	0.5	1	49	g/L			49
CA15-3	00158287	E -1	PC TM1	Ser/Pl	15608000	21.100	1.48	1	20.09	U/mL			20.09

Figure B-112 QC > Cumulative screen

The **QC** > **Cumulative** screen lists all accumulated QC results.

The list can be sorted by test name, module, and control name. The table below explains columns whose meaning is different from that on the **QC** > **Individual** screen:

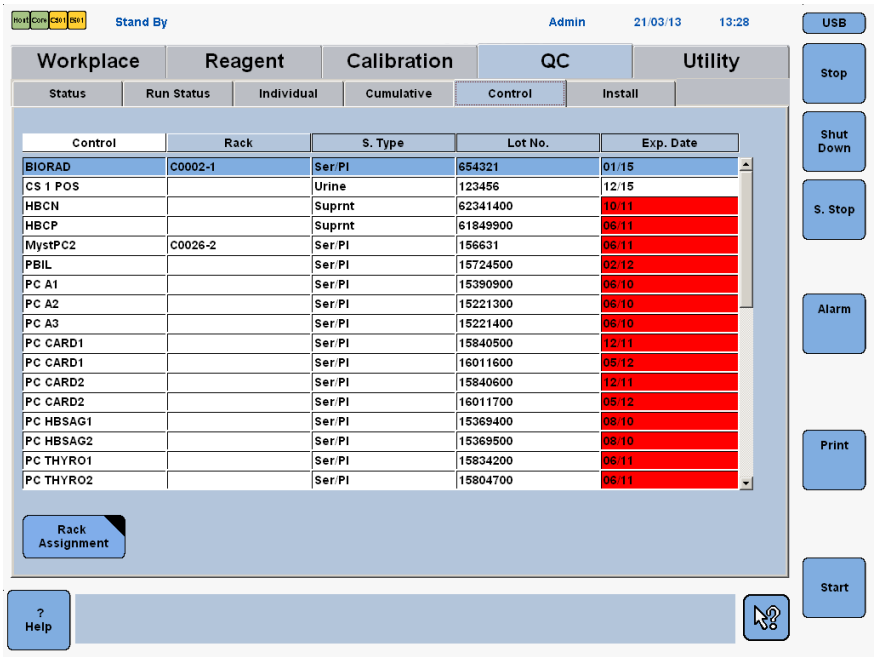
N	Number of accumulations (max. 500)
Mean	Accumulated mean for each test (using the accumulation method selected on **Utility** > **System** > **QC Setting**)

QC Control screen

The **QC** > **Control** screen provides an overview of all installed controls including the lot number and their expirations date.

When working with barcodes, controls are automatically identified. In case controls are processed in non-barcode mode, it is necessary to assign a rack number and rack position for each control. The current rack assignment is listed on the **QC** > **Control** screen.

Choose **QC** > **Control** to display this screen.



Control	Rack	S. Type	Lot No.	Exp. Date
BIORAD	C0002-1	Ser/Pl	654321	01/15
CS 1 POS		Urine	123456	12/15
HBCN		Suprnt	62341400	10/11
HBCP		Suprnt	61849900	06/11
MystPC2	C0026-2	Ser/Pl	156631	06/11
PBIL		Ser/Pl	15724500	02/12
PC A1		Ser/Pl	15390900	06/10
PC A2		Ser/Pl	15221300	06/10
PC A3		Ser/Pl	15221400	06/10
PC CARD1		Ser/Pl	15840500	12/11
PC CARD1		Ser/Pl	16011600	05/12
PC CARD2		Ser/Pl	15840600	12/11
PC CARD2		Ser/Pl	16011700	05/12
PC HBSAG1		Ser/Pl	15369400	08/10
PC HBSAG2		Ser/Pl	15369500	08/10
PC THYRO1		Ser/Pl	15834200	06/11
PC THYRO2		Ser/Pl	15804700	06/11

Figure B-113 QC > Control screen

To provide additional assignments or remove existing assignments follow the procedure on the following page.

► To assign a control to a specific rack and position

1 On **QC** > **Control** choose **Rack Assignment**.

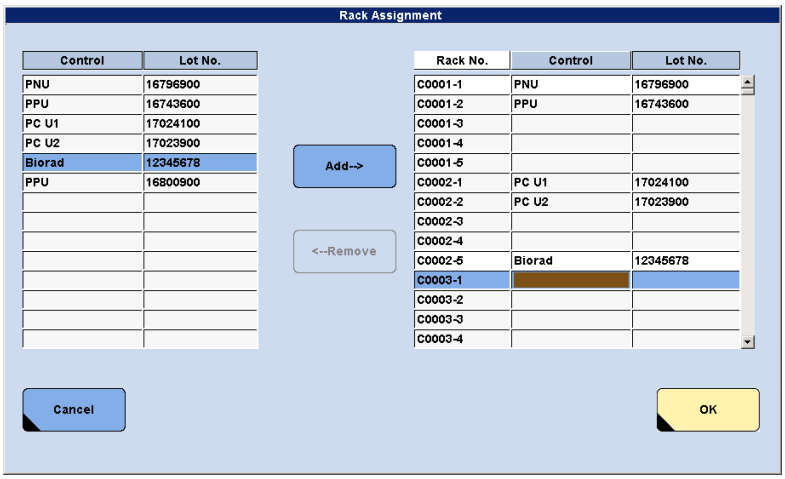


Figure B-114 QC > Control > Rack Assignment window

2 On the **Rack Assignment** window select the control from the list on the left and an unassigned rack number and position from the list on the right.

Different designations for control racks

There are following designations for the control racks:

- Rack color: white
- Label on rack: Q001 - Q999
- Software displays: C00001 - C00999 or C0001 - C0999

3 Choose **Add** to register the new assignment.

4 To remove an existing assignment select the concerned rack number and position from the list on the right and choose **Remove**.

5 Choose **OK** to save the changes and close the window.

■

Multiple rack positions for the same control (e 601)

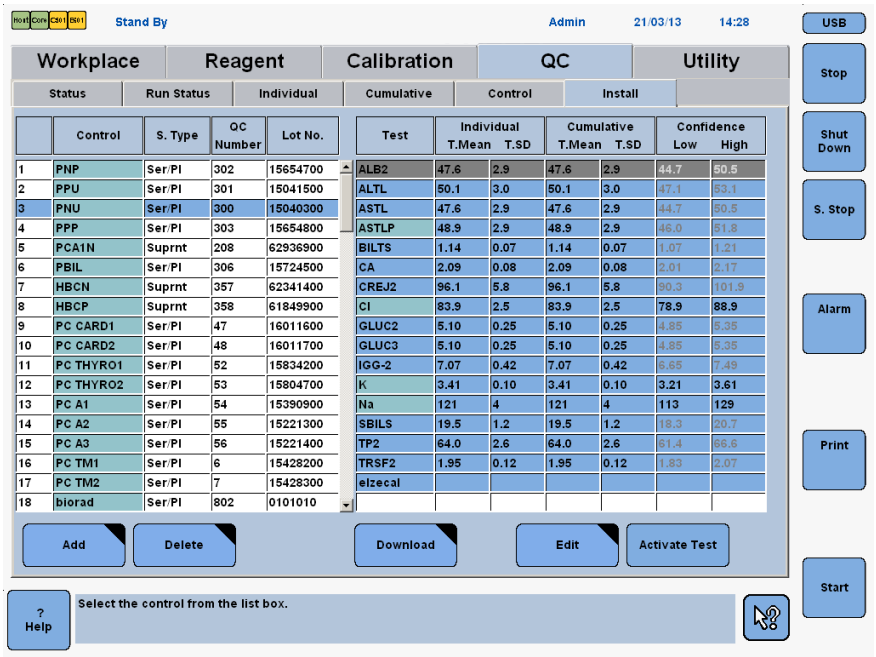
You can assign the same **e** 601 control on consecutive positions on a rack. The system will switch to the next control position if the encoded volume for one control vial is used up.

The system will not pipette the control on the next position for the same **cobas e** pack.

QC Install screen

The following sections explain certain tasks associated with the **QC** > **Install** screen. Not all tasks are described, but the most important ones are discussed here.

To display this screen choose **QC** > **Install**



	Control	S. Type	QC Number	Lot No.
1	PNP	Ser/Pl	302	15654700
2	PPU	Ser/Pl	301	15041500
3	PNU	Ser/Pl	300	15040300
4	PPP	Ser/Pl	303	15654800
5	PCA1N	Suprnt	208	62936900
6	PBIL	Ser/Pl	306	15724500
7	HBCN	Suprnt	357	62341400
8	HBCP	Suprnt	358	61849900
9	PC CARD1	Ser/Pl	47	16011600
10	PC CARD2	Ser/Pl	48	16011700
11	PC THYRO1	Ser/Pl	52	15834200
12	PC THYRO2	Ser/Pl	53	15804700
13	PC A1	Ser/Pl	54	15390900
14	PC A2	Ser/Pl	55	15221300
15	PC A3	Ser/Pl	56	15221400
16	PC TM1	Ser/Pl	6	15428200
17	PC TM2	Ser/Pl	7	15428300
18	biorad	Ser/Pl	802	0101010

Test	Individual T.Mean	Individual T.SD	Cumulative T.Mean	Cumulative T.SD	Confidence Low	Confidence High
ALB2	47.6	2.9	47.6	2.9	44.7	50.5
ALTL	50.1	3.0	50.1	3.0	47.1	53.1
ASTL	47.6	2.9	47.6	2.9	44.7	50.5
ASTLP	48.9	2.9	48.9	2.9	46.0	51.8
BILTS	1.14	0.07	1.14	0.07	1.07	1.21
CA	2.09	0.08	2.09	0.08	2.01	2.17
CREJ2	96.1	5.8	96.1	5.8	90.3	101.9
CI	83.9	2.5	83.9	2.5	78.9	88.9
GLUC2	5.10	0.25	5.10	0.25	4.85	5.35
GLUC3	5.10	0.25	5.10	0.25	4.85	5.35
IGG-2	7.07	0.42	7.07	0.42	6.65	7.49
K	3.41	0.10	3.41	0.10	3.21	3.61
Na	121	4	121	4	113	129
SBILS	19.5	1.2	19.5	1.2	18.3	20.7
TP2	64.0	2.6	64.0	2.6	61.4	66.6
TRSF2	1.95	0.12	1.95	0.12	1.83	2.07
elzecal						

Figure B-115 QC > Install screen

Use this screen to add, delete or download controls from the system and to enter or edit control values.

The list on the left of the screen displays all controls that are installed on the system. For all installed controls the control name is highlighted in green. Up to 100 controls can be installed on the system.

The list on the right of the screen displays details about the tests assigned to the control selected from the control list on the left. For a new control lot of an already installed control the activated tests are transferred.

Also calculated tests are available. Calculated tests are only displayed for Roche Diagnostics controls that are used by the tests in the calculation formula or for Non-Roche controls. For calculated tests, the control values must be determined and entered manually.

Deleting a control deletes all corresponding QC data

If you delete a control on the **QC** > **Install** screen, you also delete all corresponding QC data:

- QC > Individual
- QC > Cumulative
- QC > Run Status
- Workplace > Data Review > Routine View
- Workplace > Data Review > QC View

For information about particular tasks associated with this screen, see:
Downloading control data on page B-221
Editing control values on page B-224
Activating control tests on page B-227
Programming calculated tests on page B-292

Downloading control data

New controls may be installed on the system but the control tests are not run until they are activated from **QC** > **Install**.

See *Activating control tests* on page B-227.

To install a Roche Diagnostics control, you have to download control data from cobas link.

See *To download control data from cobas link* on page B-222.

To install a Non-Roche control, you add the control manually.

See *To add controls manually* on page B-223.

► To download control data from cobas link

1 Put the analyzer in standby.

2 Choose **QC** > **Install** > **Download** to open the **Download** window.

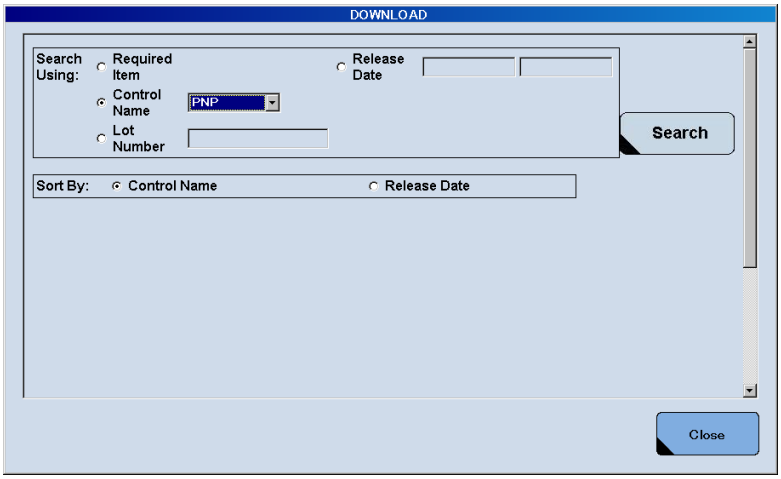


Figure B-116 Download window (tentative screen proposal)

3 Select one of the available search conditions (**Required Item**, **Calibrator Name**, **Lot Number**, or **Release Date**) in the **Search Using** area.

- **Lot Number** is the recommended search condition.

 Enter the first six digits of the lot number followed by two zeros.

- The option **Release Date** refers to the date when the calibrator was released by Roche Diagnostics.

4 Select **Release Date** in the **Sort By** area to sort the displayed search results by the release date.

5 Choose **Search**. A list of items that meet the given search conditions appears.

Several search results

If the **Download** window displays several search results, note the following:

- Choose **[Next >]** to display more search results.
- Use the scroll bar on the right side to display the **Download** button.

6 Select the check box(es) in the **Selection** column to download the necessary control information and choose **Download**.

Download latest version

Always download the latest version of control data. Select **Release Date** in the **Sort By** area to change the display order and select the control data with the latest **Release Date**.

7 Confirm the message on the confirmation windows to start the download.

All necessary information, such as applications covered by the control, target mean values, and target SD values, is automatically stored by the system.

■

To run control tests with a newly installed control it is necessary to activate these tests.

See *Activating control tests* on page B-227.

If necessary it is possible to edit the downloaded target values and/or confidence limits.

See *Editing control values* on page B-224.

► To add controls manually

1 Select a blank line from the control list on the **QC** > **Install** screen.

2 Choose **Add**.

3 Type all necessary data in the **Add Control** window.

The **Material No** range is from 801-999.

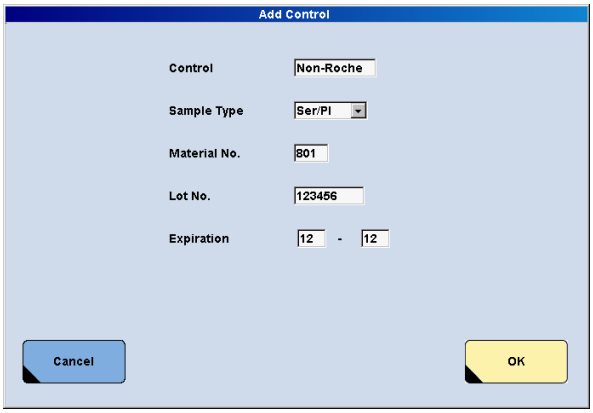


Figure B-117 Add Control window

4 Choose **OK**. The new control appears on the control list.

To run control tests with the newly installed controls, it is necessary to manually enter the target values for each test and then to activate these tests.

5 Choose **Edit** to enter target mean, target SD, and confidence limits if necessary.

6 Choose **Active Test** to activate the tests for the new control.

For more details see:
Editing control values on page B-224
Activating control tests on page B-227

■

Editing control values

This section describes how to edit the control values.

► To edit control values

1 On the **QC** > **Install** screen choose the control lot to be edited in the **Control** list on the left-hand side of the screen.

2 Choose **Edit** to display the **Edit Control** window.

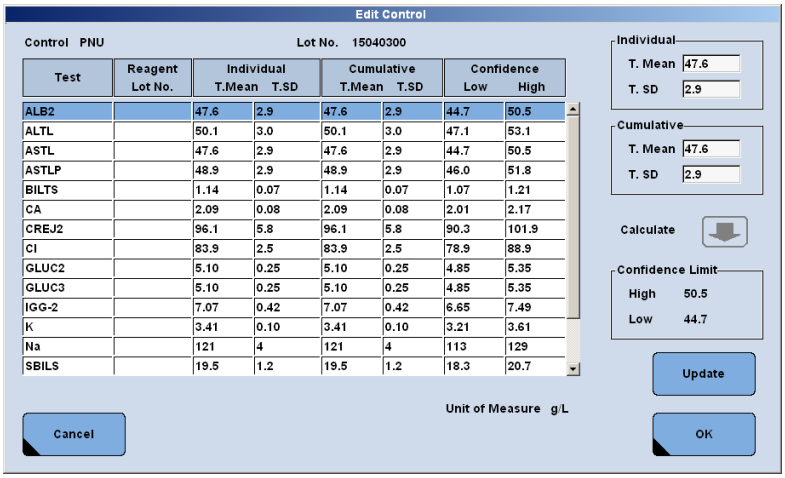


Figure B-118 Edit Control window

3 Select the test to be edited from the list. For the **e** 601 you must also select the reagent lot number. Target values for **e** 601 tests are reagent lot specific.

4 Type the new target mean and SD (standard deviation) values, cumulative and individual, in the appropriate text boxes.

If the test uses this control for its QC Violation assessment, the **Calculate** button is active; if not skip step 5.

For more information on QC violation, see *QC-triggered calibration (QC Violation)* on page B-157.

5 Choose **Calculate** to recalculate the confidence limits on the basis of the edited target and SD values and the QC violation rule (set under **Utility** > **Application** > **Calib**.).

6 Choose **Update** to update the window.

7 Repeat steps 3 to 6 for all tests assigned to this control that need to be edited.

8 Choose **OK** to save the changes and close the **Edit Control** window.

■

In case target and SD values are edited or entered manually the calculation of confidence limits is achieved by choosing the **Calculate** button. However, the confidence limits can also be typed directly in the text boxes under **Confidence Limit**.

The **Calculate** button and the boxes **High** and **Low** are not available if the selected test is not configured for **QC Violation**.

No update of manually edited control values

In case a value has been manually edited, this value will not be updated when you download new control values from **cobas** link. There is no indication in the software if the value was manually edited before.

- Check the control values after downloading.
- If you want to return to the original control value, delete the control and download it again from **cobas** link. Perform control measurements before you resume routine operation.

Updating of control values

In case of a reassignment of control values, the control values of the **cobas** 6000 system have to be updated.

- At the **c** 501 the new control values can be downloaded, or manually updated.
- At the **e** 601 the new control values are automatically updated via **cobas e** pack barcode, or can be manually updated.

No update of manually edited control values

In case a value has been manually edited, this value will not be updated when you download new control values from **cobas** link. There is no indication in the software if the value was manually edited before.

- Check the control values after downloading.
- If you want to return to the original control value, delete the control and download it again from **cobas** link. Perform control measurement before you resume routine operation.

*Updating the control values via **cobas e** pack barcode*

If the lot of the **cobas e** pack is newer than the installed controls, the reassigned control values are updated automatically via the barcode of a **cobas e** pack. The barcode of a **cobas e** pack contains the control values for specific reagent lot and control lot combination and it will be only used, if this lot combination is used on the system.

*Updating the control values manually (**e** 601)*

If both the **cobas e** pack and the control are already on the market, and reassigned control values are established for this reagent lot and control lot combination, then the customer has to update these values manually in the software. The customer will be informed about this task by an Important Note in the **cobas** e-library.

► To Update control values for c 501 via download

1 Download the control that needs to be updated. Ensure that you download the control data with the latest release date.

The new values automatically overwrite the old values.

👁 See *Downloading control data* on page B-221.

■

No update of manually edited control values

In case a value has been manually edited, this value will not be updated when you download new control values from **cobas** link. There is no indication in the software if the value was manually edited before.

- Check the control values after downloading.
- If you want to return to the original control value, delete the control and download it again from **cobas** link. Perform control measurement before you resume routine operation.

► To update control values manually

1 Enter the control values for the reagent and control lot combination according to the Important Notice from **cobas** link on the **Edit Control** window.

👁 See *Editing control values* on page B-224.

The new control values are communicated via product bulletin and Important Note in the **cobas** e-library.

■

No update of manually edited control values

In case a value has been manually edited, this value will not be updated when you download new control values from **cobas** link. There is no indication in the software if the value was manually edited before.

- Check the control values after downloading.
- If you want to return to the original control value, delete the control and download it again from **cobas** link. Perform control measurement before you resume routine operation.

Activating control tests

Only if controls are activated for the corresponding test the measurement will be performed. Tests can only be activated when the system is in standby.

► To activate control tests

1 On the **QC** > **Install** screen choose the appropriate control name in the list box on the left side of the screen.

2 Choose all tests to be activated in the list on the right of the screen.

3 Choose **Activate Test**. The test name highlights in green when the test is activated.

■

To activate a test, it must have target and SD values entered for the control.

See *Editing control values* on page B-224.

Automatic QC measurement

When a control interval time is specified on **Utility** > **Application** > **Range** for an application, it is possible to let the system automatically perform necessary QC measurements with controls that permanently stay in the rack rotor.

Configuring automatic QC measurement

This section describes how to configure automatic QC measurement.

► To program auto QC measurements

1 Select the **Control Interval Time** check box on the **Range** tab of **Utility** > **Application** for the relevant tests and specify a control interval from 1 to 1000 hours.

2 Reserve one or more rack rotor positions for control racks under **Utility** > **System** (**Page 3/4**) > **Rack Delivery**.

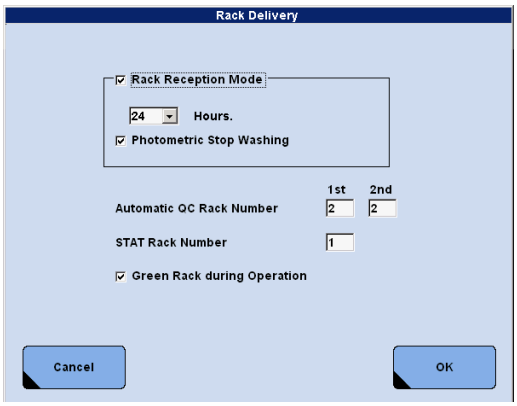


Figure B-119 Rack Delivery window

3 Assign a rack range for control racks that are to be used for auto QC measurements:

- Choose **Utility** > **System** > **Change** (**Rack Assignment** area).
- In the **Rack Assignment** window, choose the **Module Setting** tab and enter the rack range in the **Rotor** text fields.

■

When loaded onto the analyzer, the assigned control racks stay in the rack rotor and are used whenever a QC measurement is requested and the auto QC rack holds the appropriate control material.

If you load a fresh QC rack, the freshest one (the QC rack that has been loaded last) is always used for Auto QC.

An asterisk (*) in the first column of the **QC** > **Status** screen denotes which control is used as automatic QC.

👁 See *Module Setting tab* on page E-371.

Unloading auto QC racks from the rack rotor

This section describes how to unload auto QC racks from the rack rotor.

► To unload auto QC racks from the rack rotor

1 Choose **QC** > **Status** > **Automatic QC Unloading**.

2 In the **Automatic QC Unloading** window select the rack(s) to be unloaded and choose **Select**.

3 Choose **Execute**.

■

Expired controls in auto QC racks

- If you use auto QC racks and a control expires (the on board stability set on the **Utility** > **Application** > **Range** tab is exceeded), the system issues a yellow alarm. Additionally on the **QC** > **Status** screen, the first column of the corresponding control turns yellow.
- Unload the concerned auto QC rack, replace all controls, and reload the rack onto the analyzer.
- If you do not replace an expired control, the analyzer continues to use this control, which results in unreliable quality controls.

Priority within control materials of the same kind

- When there is more than one control available for a QC measurement, the system uses the control with the longest on board stability.
- If for example, an automatic QC rack is loaded for QC after calibration and this rack holds a control that is already present in an auto QC rack in the rack rotor, the auto QC control is not used if the additionally loaded control has a later expiration date.

Extended operation

This chapter contains additional information and tasks which are usually not required during normal routine operation.

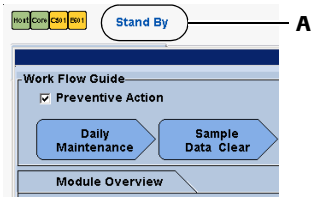
In this chapter *Chapter* 13

Instrument status B-233
Interlock function: Reset after stop B-235
Masking functions B-236
T-masking and P-masking B-237
Module masking B-237
Reagent masking B-238
Calibration masking (auto masking) B-239
Backup operation B-240
Activating backup operation mode B-240
Measuring samples in backup operation mode B-242
Data storage B-244
Preparing a DVD disk B-244
Formatting a DVD disk B-245
Making a DVD disk compatible (Windows XP control units only) B-246
Using a USB storage device B-247

Table of contents

Instrument status

This section explains the most important operational statuses (modes). The status is displayed in the upper left of the monitor.



A Current instrument status

Figure B-120 Current instrument status

The following table shows the most important statuses:

Status	Explanation
Backup Wait For Rack Setting	Status for the backup operation mode. In this status, you have to place the sample racks through a door at the back of the **c** 501 module into the backup operation port. Intended to be used when a problem occurs in the rack sampler and a rack cannot be conveyed.
Initialize	Status while the instrument performs any kind of initialization. • After **Power Up**
Maintenance	Status while the instrument is performing any software-controlled maintenance item or check.
Operation	Status while the instrument is pipetting, measuring, or calculating. During this status it is not possible to change any settings in the software.
Parameter Check	Status in which the instrument checks the **c** 501 application parameters (**Utility** > **Application** > **Other**).
Pipe	Status in which a maintenance pipe is being executed.
Post Operation	Status after operation in which the instrument performs any kind of post operation. • Measurement cells are filled with system water (**e** 601). • All **cobas e** pack caps are closed to soft-close position (**e** 601).
Power Up	Status while the instrument is loading programs, performing self-checks, etc. • After starting the software • Before **Initialize** This status is not displayed in the status line.
Power Up Pipe	Status in which the instrument is performing the software-controlled maintenance power up pipe.
Preparation	Status while the instrument prepares any kind of reagent, checks incubator bath levels, and performs any kind of reset. • Tubings of ProCell and CleanCell • Priming of PreClean • Two times emptying and refilling of the reservoirs of ProCell and CleanCell • Checking the incubator positions by the gripper • Performing initial microbead mixing by the microbead mixer

Table B-29 Instrument statuses (Sheet 1 of 2)

Status	Explanation
Rack Collect End	Status after **Rack Supply Complete**. If the instrument works in the **Rack Reception Mode**: After all test requests are completed and the racks are all in the unloader. The instrument waits for additional samples. New samples will be processed automatically after pressing the **Start** button. If the instrument works in **MPA Connection Mode**: The system also changes to this status when **S.Stop** has been pressed.
Rack Collect End (Restart Disabled)	Status after a hardware problem occurred, e.g., rack stuck in the loader. If **Green Rack during Operation** is disabled: After inserting the green wash rack in automatic mode.
Rack Supply Complete	Status after the racks were loaded into the instrument. The rack loader tray is empty.
Reagent Dump	Status while a **c** 501 module dumps a **cobas c** pack.
Reagent Registration	Status while a **c** 501 module loads a new **cobas c** pack or an **e** 601 module registers a new **cobas e** pack.
Reagent Unloading	Status while a **c** 501 module unloads a **cobas c** pack.
Reconnect	Status after the module was in **Power Off** status and activated again (**Utility** > **Module Set** > **Module Setting**).
Shut Down	Status after pressing the **Shut Down** button. The system and control unit are disconnected. Power for keeping the reagents cool is still supplied.
Sleep	Status of low energy in which no immediate processing can be initiated by the operator.
Stand By	Status when the instrument does not perform any measurement activities. Settings can be changed and new information can be downloaded from **cobas** link.
Start Up Pipe	Status in which a maintenance start up pipe is being executed.
Stop	Status after the system was stopped. A system stop can be due to a hardware failure or because any of the safety devices requested an emergency stop. It can also be initiated by the operator pressing the **Stop** button. The system requires either a complete power off or at least a reset (**Utility** > **Maintenance**) to resume normal operation.

Table B-29 Instrument statuses (Sheet 2 of 2)

Interlock function: Reset after stop

If you open the top cover of the **c** 501 module, the interlock function stops all moving parts immediately and an alarm is issued. If you want to continue operation or perform a maintenance item, you have to put the instrument back to standby.

See *Interlock function* on page A-31.

► To release the analyzer in standby status after interlock

1. Close the top cover of the **c** 501 module and lock it.
2. Choose **Stop** (global button).
3. Choose **Yes** and confirm with **Yes**.
4. If an error message is displayed that the top cover was opened, delete this error message.
5. Choose **Utility** > **Maintenance**.
6. Select **Maintenance** (1) from the **Maintenance Type** list on the left.
7. Select **(1) Reset** from the **Maintenance** Items list on the right.
8. Choose **Select** to open the **Reset** window. Select the **c** 501 module to be reset.
9. Choose **Execute**.

■

Masking functions

Generally speaking, masking is a function that allows temporary exclusion of the masked element from analysis. Some types of masking are set automatically by the instrument depending on specific conditions, other types are manually set by the user.

The following table provides an overview of the masking functions:

Masking function	Use	Notes	Page
T-masking and P-masking	To disable analysis of a test or samples, e.g., until calibration or QC is performed	Manual	B-237
Module masking	To disable a single module for background maintenance or for loading of reagents	Manual	B-237
Reagent masking	To disable analysis of a test if a required reagent is empty	Automatic	B-238
Calibration masking (Auto masking)	To disable analysis with reagent for which a calibration failed or a calibration is requested due to reagent changeover	Automatic (if configured)	B-239

Table B-30 Masking functions



Requesting masked tests

Masked tests can be requested but not measured until the test is unmasked. Masked tests are indicated on the **Workplace** > **Test Selection** screen.

T-masking and P-masking

T-masking and P-masking are used to exclude specific tests from the current analysis.

There are two possibilities to mask a test:

- If **T-Mask** is selected, no patient samples, no controls, and no calibrations can be performed.
- If **P-Mask** is selected, the test is masked for patient samples only—calibration and QC can be performed.

Tests can be masked completely or just for specific modules and measuring cells. Masking tests on specific modules or measuring cells may be reasonable, for example, at times with reduced throughput (evenings, weekends) in order to save calibrators, controls, and time.

For a detailed description of the **Masking** window, see *Masking window* on page E-195.

► To mask a test

1 Choose **Start** (global button) > **Masking**.

The **Masking** window shows the registered tests in the left column, the other columns represent the **c** 501 modules or measuring cells of the **e** 601 modules.

2 Mask a test completely, or just for an individual measuring cell:

- Select a test in the **Name** column.
- Choose the **T-Mask** button beneath the **Name** column to mask the complete test, or choose the **T-Mask** button beneath the module or measuring cell column to mask an individual module or measuring cell.

 The mask button toggles between **T-Mask**, **P-Mask**, and **Unmask**.
- Choose the mask button repeatedly to toggle between **T-Mask**, **P-Mask**, and **Unmask**.

3 For **e** 601 modules: If a test is masked on one measuring cell, select the **mask on scheduling within module** check box to allow the system to mask the selected cell as soon as all pipetted samples are measured.

■

Module masking

The module masking function is used to disable an individual module. A masked module goes into standby. Certain maintenance items can be performed on a masked module while the other modules are still processing samples (so-called background maintenance).

For loading **cobas e** packs, ISE Ref., and some auxiliary reagents the corresponding module must be in standby. Module masking allows loading of reagents on one module while the others are operating.

For information on module masking for background maintenance, see Chapter 15 *General maintenance*.

Reagent masking

When a reagent is used up, the system issues an alarm and a red bar is displayed on the test key on the **Test Selection** screen. Tests that require this reagent are masked by reagent masking—unless another reagent pack is available as a standby reagent.

- Reagent masking is applied to:
 - Photometric and immunologic assay reagents
 - ISE reagents
 - Pretreatments
 - Reagent probe detergents
- Reagent masking is NOT applied to:
 - Reaction cell detergents
 - Diluent
 - EcoTergent

The test will be unmasked automatically as soon as you load new reagent. After registration, check the reagent volume, number of available tests, etc. on **Reagent** > **Setting**.



Rerun required in case of reagent masking

A rerun is required for samples whose sampling was terminated by reagent masking. Take the sample rack concerned from the unloader, place it into the rack loader and perform a rerun measurement. These samples will be shown as failed for the 1st run.

Calibration masking (auto masking)

Automatic calibration masking is a function that masks a **cobas c** pack or **cobas e** pack for a module or measuring cell when no valid calibration is available for this particular module or measuring cell.

This function is activated (or deactivated) for the entire system under **Utility** > **System** (**Page 2/4**) > **Calib Mask Setting**. When activated, the function can be selected individually for each application on the **Calib.** tab of the **Utility** > **Application** screen. This setting is set as the default in the applications.

Failed calibrations

When a calibration is successful, the calibration data are available for the measurement of patient samples and controls. When a calibration fails one or more quality criteria, this calibration gets the status *Failed*. *Failed* calibration data is not available for the corresponding **cobas c** pack or **cobas e** pack.

If automatic calibration masking is activated, the corresponding test with the *Failed* calibration is masked. If automatic calibration masking is not activated, the test is not masked but data alarms are attached to the results.

cobas c pack changeover

When a changeover request is present and automatic calibration masking is not activated, this **cobas c** pack will work with the last valid lot calibration data for this test (newest calibration). No alarm is attached to this result.

See *Newest calibration* on page B-161.

Reject button

The *Failed* calibration can be *rejected* by the operator (**Reject** button on **Calibration** > **Status**) so that the latest successful calibration, if it exists, is used for the upcoming samples and controls.

Backup operation

The backup operation mode can be useful if the rack loader/unloader or the rack rotor cannot convey any samples. This mode enables sample measurement on **c** 501 modules to continue.

In backup operation mode, only routine and STAT samples can be processed (including rerun samples).

- Backup operation mode is available only if barcode mode is selected and only on one **c** 501 module at a time.
- Backup operation mode is only available when the rack loader/unloader, rack rotor and the conveyor have been inactivated (**Utility** > **Module Set**).
- Backup operation mode is not available on **e** 601 modules.

Activating backup operation mode

Before using the backup operation mode, the rack rotor needs to be inactivated in the analyzer software.

► To inactivate the rack rotor

1 Choose **Utility** > **Module Set**.

2 Choose **Module Setting**.

3 Choose **Rack Rotor** to inactivate the rack rotor. The color of the **Rack Rotor** and **Conveyor** buttons changes to dark green.

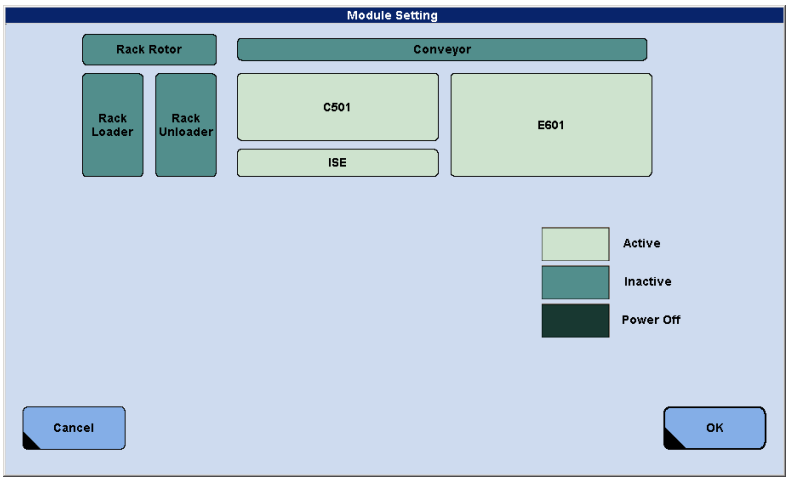


Figure B-121 Module Setting window

4 Choose **OK** to save the changes.

■

► To activate the backup operation mode

1 On the **System Overview** screen, select the **c** 501 module on which the samples should be processed.

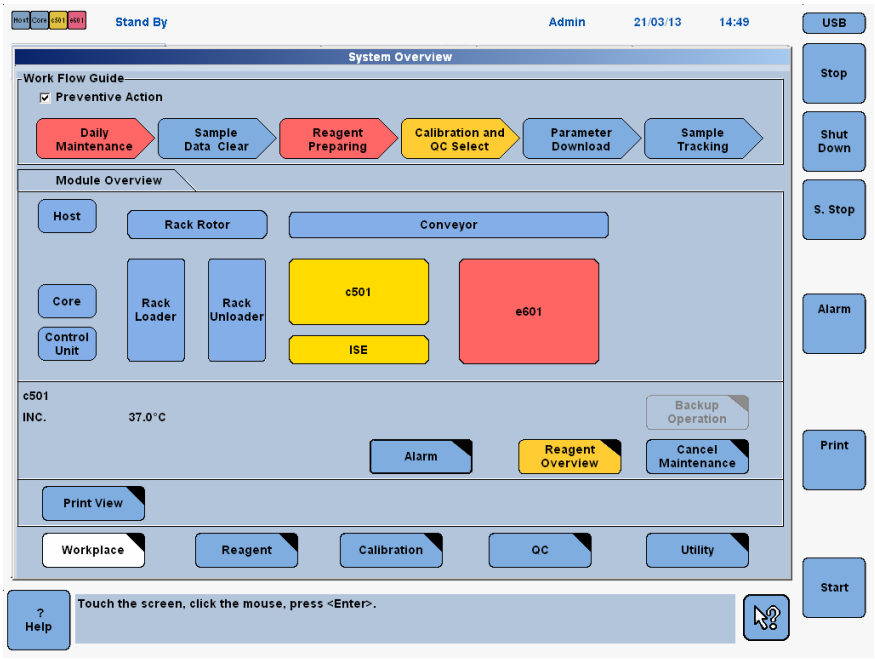


Figure B-122 System Overview window

2 Choose **Backup Operation**.

3 Choose **Start** on the **Backup Operation** window.

4 When the instrument goes into *Backup Wait For Rack Setting* status, the instrument is ready to measure samples.

See *Measuring samples in backup operation mode* on page B-242.

■

Measuring samples in backup operation mode

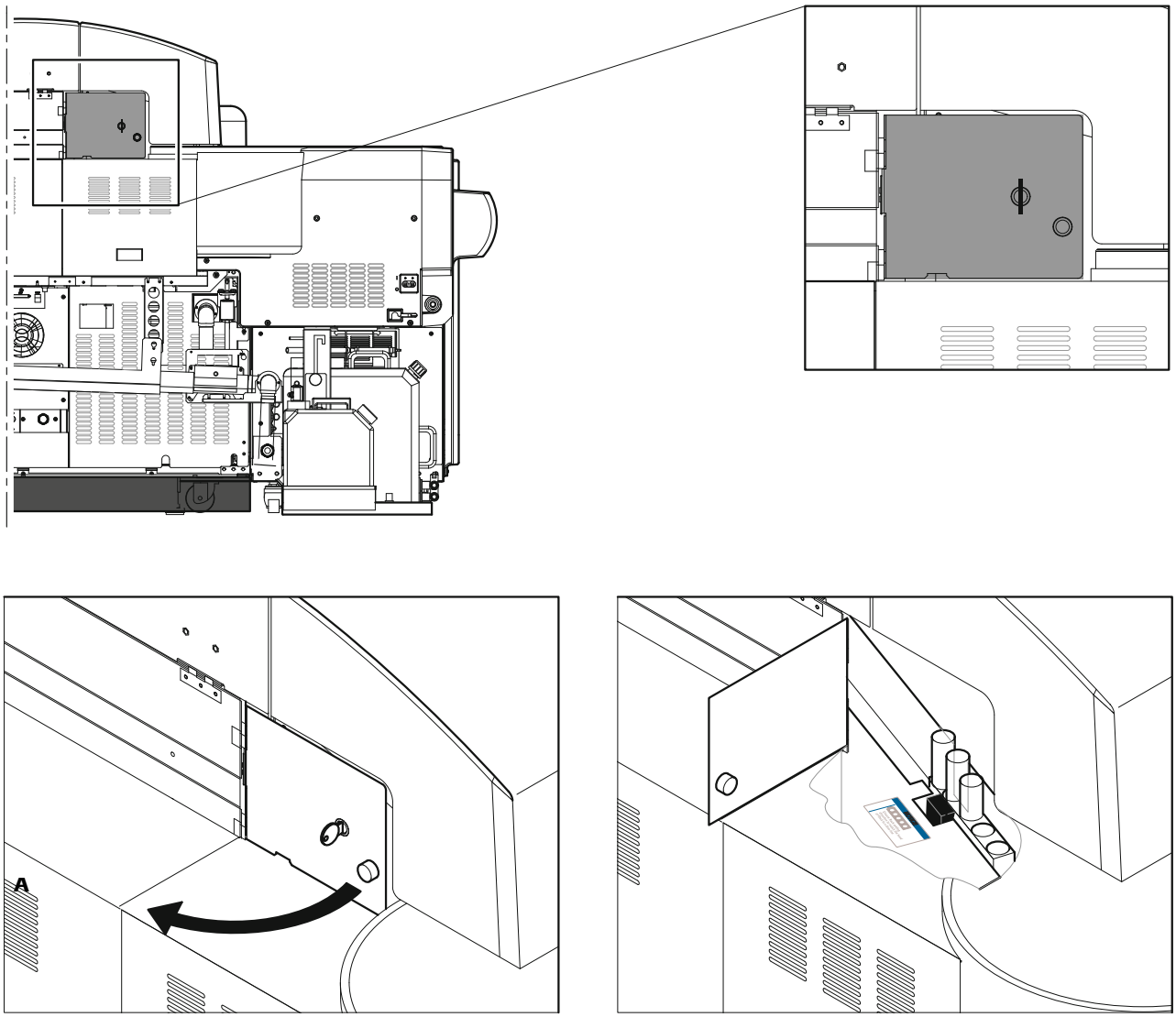
Tests can be selected similar to routine operation, either from the **Test Selection** screen or via Host.

In this mode, you have to place the sample racks through a door at the back of the **c** 501 module into the backup operation port.

► To measure samples in backup operation mode

1 Activate the backup operation mode.

See *Activating backup operation mode* on page B-240.

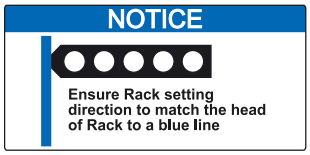


A Back door **B** Correct position of the rack

Figure B-123 Placing a rack into the backup operation port

2 Unlock and open the back door.

3 Place a rack containing barcoded samples into the backup operation port.



4 Check the position and direction of the rack:

- Align the left side of the rack with the blue line on the label.
- The sample barcodes must be oriented towards the instrument.

If the rack position or direction is wrong, an alarm will be issued.

5 Close and lock the back door.

6 After sample pipetting is completed and the instrument is in Stand by or in *Backup Wait For Rack Extraction* status, remove the rack through the back door.

To perform continuous measurement, remove the rack during *Backup Wait For Rack Extraction* status, place the next rack to be measured, and choose **Start**.

7 Repeat steps 1 to 6 until all sample racks are measured.

■

Data storage

All backup operations can be done on DVD disks or USB storage devices. DVD disks have to be prepared before using. For using a USB storage device, observe the given information.

Both storage media, DVD and USB storage device, are defined as mass storage in the software. If you choose **Mass Storage**, the instrument decides the medium depending on following rules:

- If a USB storage device is inserted, the instrument uses the USB as mass storage.
- If no USB storage device is inserted, the instrument uses a DVD disk as mass storage.

Preparing a DVD disk

cobas 6000 control unit computers are optionally equipped with a DVD disk drive. The DVD disk drive can be used for installing software updates and backing up and restoring data.

See *Archiving patient data* on page B-91.

The following DVD formats can be used:

- DVD-R
- DVD+R
- DVD-RW
- DVD+RW

DVD disks require formatting before use.

See *Formatting a DVD disk* on page B-245.

Any DVD from a **cobas** 6000 control unit running under Windows 7 can be read on other Windows 7 computers without any further steps. The DVDs are made compatible automatically.

If the **cobas** 6000 control unit uses the Windows XP operating system, follow the *Making a DVD disk compatible* procedure if you want to read the DVD on another computer other than a **cobas** 6000 control unit.

See *Making a DVD disk compatible (Windows XP control units only)* on page B-246.

Any DVDs created on a **cobas** 6000 Windows XP control unit can be read on a **cobas** 6000 Windows 7 control unit without any further steps.

Formatting a DVD disk

Danger of data loss

Formatting a DVD-RW or DVD+RW disk deletes all data on the disk.

- Before formatting a DVD disk, make sure that no important data is stored on the disk.

DVD-R and DVD+R disks can be formatted once only. DVD-RW and DVD+RW disks can be formatted several times.

- The DVD disk is formatted with UDF (Universal Disk Format). The DVD disk cannot be read on computers that do not support UDF.
- The procedure for formatting a DVD disk may differ, depending on the configuration of your system.
- Only format DVD disks on the **cobas** 6000 control unit computer. The **cobas** 6000 control unit computer may not be able to read DVD disks formatted on any other computer.

► To format a DVD disk

1. Make sure the analyzer is in standby.
2. Insert a new DVD disk into the DVD drive.
3. Press <Ctrl>+<F7> to display the **Format** window.
4. Choose **Quick (erase)** or **Full** from the **Format type** area.

 Depending on the type of DVD disk only **Full** is available.
5. Choose **Start** and confirm the formatting process with **OK**.

 The DVD disk is formatted. This may take several minutes.
6. After formatting is finished confirm with **OK**.

 The DVD disk is ready for a data backup now.

■

Making a DVD disk compatible (Windows XP control units only)

If you want to use a DVD+R or DVD-R disk on another computer than the **cobas** 6000 control unit computer, the DVD disk must be made compatible (*finalized* or *closed*).

After making the DVD disk compatible, no more data can be stored on the DVD-R or DVD+R disk. The disk is *finalized*.

A DVD-RW disk can be used on other computers without being made compatible.

► To make a DVD disk compatible

1. Make sure the analyzer is in standby.
2. Insert the DVD disk into the DVD drive.
3. Press <Ctrl>+<F8> to display the **Compatibility** window.
4. Choose **Start** and confirm the process with **OK**.

 The DVD disk is made compatible. This may take several minutes.
5. After making compatible is finished confirm with **OK**.

 The DVD disk is ready to be used on other computers.

■

Using a USB storage device

USB storage devices can be used for several kinds of data backups and restores. Wrong handling of a USB storage device may result in data loss or malfunction of the instrument.

- Insert or remove a USB storage device only when the instrument is in standby mode.
- At any one time only one USB storage device can be in use. Before inserting a USB storage device, check that no other USB storage device is inserted.
- Only remove USB storage devices after choosing **USB** (global button).
- Use only USB storage devices that are tested by your local Roche service representative.

► To plug in a USB storage device

1 Ensure the instrument is in standby.

2 Ensure that no other USB device is plugged into the control unit computer.

3 Plug the USB storage device into any USB port of the control unit computer.

■

► To remove a USB storage device

1 Ensure the instrument is in standby.

2 Choose **USB** (global button).

3 Confirm with **Yes**.

4 Remove the USB storage device.

■

Device and data management

Although at any time only one USB storage device can be in use, for different data different USB storage devices can be used. Roche Diagnostics recommends to use three USB storage devices to manage the backup of the instrument data:

- Device 1 for patient and QC result backup
- Device 2 for backup of system parameter
- Device 3 for temporary use

Data	Corresponding screen	Folder	File name and extension	Device 1	Device 2	Device 3
Patient data	**Workplace** > **Data Review** > **Backup Data**	7600	Binary: xxx.res xxx.smp ASCII: xxx.asc	×		
QC data	**Workplace** > **Data Review** > **Backup Data**	7600	Binary: xxx.res xxx.smp ASCII: xxx.asc	×		
FD Parameter	**Utility** > **Maintenance** > **Maintenance** > **(15) Parameter Read/Write**	7600	25 paramter files		×	
Print buffer	**Print** (global button) > **View** > **Media Write**	7600	xxx.txt			×
Trace doc	**Utility** > **Maintenance** > **Maintenance** > **(40) Trace Doc Export**	TraceDoc	SVP_TRANS_4_ YYYYMMDDHHMI.zip YYYY = year MM = month DD = day			×

Table B-31 Recommended use of storage devices

Configuration

This chapter describes the configuration of the **cobas** 6000 analyzer series for customers.

In this chapter *Chapter* 14

Application B-251
Overview B-251
Installing an application B-252
Downloading new application parameters B-255
Updating an application B-258
Description of application parameters B-260
Description of application parameters – Analyze tab B-261
Dilution ratios (e 601) B-262
Description of application parameters – Calib. tab B-263
Duplicate limit (e 601) B-264
Auto masking B-265
Auto calibration B-265
Description of application parameters – Range tab B-267
Unit of measure B-269
Report name B-271
Automatic rerun B-271
Technical limit (c 501) B-272
Repeat limit B-272
Control interval time B-272
Automatic QC on board stability B-272
Qualitative fields (c 501) B-273
L, H, I (serum index, c 501) B-273
Expected values B-274
Description of application parameters – Other tab (c 501) B-275
Setting up individual calibration curves for each ISE sample type B-276

System configuration B-277
Programming system parameters B-278
Generating multiple results for a single test B-280
Assigning tests or profiles to test keys B-281
Maintenance / Pipe Setting / Power Up Pipe buttons B-284
Rack Delivery button B-284
Module Set B-287
Assigning a test to a module B-288
Inactivating a module B-290
Calculated Tests (c 501) B-291
Programming calculated tests B-292
Programming compensated tests B-295
Special Wash B-297
Programming a special wash for c 501 modules B-297
Reagent probe wash B-298
Cell wash B-300
Sample probe wash B-302
Programming a special wash for e 601 modules B-304
Reagent probe wash B-304
Sample probe wash B-305
Report Format B-306
Customizing patient report format B-306
Comparison of data monitor format and report format B-309
Data Monitor/Report (monitor format) B-309
Data Monitor/Report (report format) B-309
Saving system parameters B-310
Restoring system parameters B-312

Application

All required applications were installed during system installation by your Roche service representative. This section explains how to add new applications and configure specific application parameters.

Overview

General information for photometric tests

Up to 117 photometric applications can be registered (test numbers 1-117). The following test numbers are fixed:

118	Na
119	K
120	Cl
121	Serum index L
122	Serum index H
123	Serum index I

General information for immunological tests

Up to 60 heterogeneous immunoassays can be installed irrespective of the number of modules (test number 141-200). An application can be programmed for each module and measuring cell (E1-1, E1-2 and E2-1, E2-2) individually.

Downloading a new application

Before you can load the corresponding **cobas c** pack or a **cobas e** pack for a new application, the application parameters have to be downloaded via **cobas** link. Otherwise, the **cobas c** pack will be rejected by the system and the **cobas e** pack test will not be displayed correctly on different screens of the **Reagent**, **Calibration**, and **Utility** menu.

For more information, see *To configure the application data* on page B-252.

Installing an application

The **cobas** 6000 analyzer series requires application parameters, calibrator data, and control data for each application. All data required for a new application can be downloaded from **cobas** link.

Additional settings In addition, various settings and customizing of default parameters are required to complete the installation.

Required operator level Most operations of installing an application can be performed by an operator with administrator level. However, some operations require an operator with supervisor level.

See *Overview of access levels* on page E-403

Installing procedures To install an application, you have to perform the following procedures:

- *To configure the application data*
- *To configure the calibrator data*
- *To configure the control data*
- *To configure additional settings*
- *To finalize the installation*

► To configure the application data

1 Download the application parameters.

For more information, see *Downloading new application parameters* on page B-255.

2 Customize the application parameters.

- Optional

For more information, see *Description of application parameters* on page B-260.

3 Assign the application to a module.

For more information, see *Assigning a test to a module* on page B-288.

4 Assign the application to a test key or profile.

For more information, see *Assigning tests or profiles to test keys* on page B-281.

5 Define the reagent warning levels.

- Optional, but recommended

For more information, see *Reagent Level Check window* on page E-388.

6 Define an application specific-instrument factor, as stated in the instructions for use for individual tests.

- Only necessary for certain **c** 501 applications, for example Creatinine Jaffé

■

► To configure the calibrator data

1 Download the calibrator data.

👁 For more information, see:
To download calibrator data from cobas link on page B-186
ISE calibration on page B-193

2 Edit the decimal places or the calibrator concentration values of the calibrator.

- Only possible for **c** 501
- Optional

👁 For more information, see:
Editing calibrator concentrations (c 501) on page B-189
Changing decimal places used for reportable data (c 501) on page B-191

3 Assign the rack positions for the calibrator.

- Only necessary if you are working with non-barcoded calibrators

👁 For more information, see *Assigning calibrator positions* on page B-178.

■

► To configure the control data

1 Download the control data.

👁 For more information, see *Downloading control data* on page B-221.

2 Activate the control for the new test.

👁 For more information, see *Activating control tests* on page B-227.

3 Assign the rack positions for the control.

- Only necessary if you are working with non-barcoded controls

👁 For more information, see *To assign a control to a specific rack and position* on page B-219.

4 Configure an automatic QC measurement for the control.

- Optional

👁 For more information, see *Configuring automatic QC measurement* on page B-228.

■

► To configure special wash

1 Check whether special washes are necessary and, if required, program the special washes.

- **c** 501 tests: Refer to the latest instructions for use for NaOH-D / SMS / Sample Cleaner 1 or 2 / SCCS (Special wash requirements method sheet).

 👁 For more information, see *Programming a special wash for c 501 modules* on page B-297.

- **e** 601 tests: Contact your Roche service representative.

 👁 For more information, see *Programming a special wash for e 601 modules* on page B-304.

■

► To configure additional settings

1 Customize the patient report format.

- Optional

👁 For more information, see *Customizing patient report format* on page B-306.

2 Program a calculated test.

- Only possible for **c** 501
- Optional

👁 For more information, see *Programming calculated tests* on page B-292.

■

► To finalize the installation

1 Load the **cobas c** pack or the **cobas e** pack.

👁 For more information, see:
To load a cobas c pack on page B-49
To load cobas e packs on page B-50

2 Calibrate the application and perform QC measurements.

👁 For more information, see:
Requesting and cancelling calibrations manually on page B-167
Requesting QC measurements on page B-205

3 Add the new applications to the **Preferences** of the **cobas** e-library (**cobas** link).

👁 For more information on working with the **cobas** e-library, refer to the **cobas** e-library Operator's Manual.

4 Make a backup of the system parameters after finishing the installation of all new applications.

👁 For more information, see *Saving system parameters* on page B-310.

■

Downloading new application parameters

The following procedure describes how you can download new application parameters from **cobas** link. It can be performed by an operator with administrator level password only.

► To download application parameters from cobas link

1 Choose **Utility** > **Application** to display the **Application** screen.

2 Choose **Download** to start the download of information about additional applications.

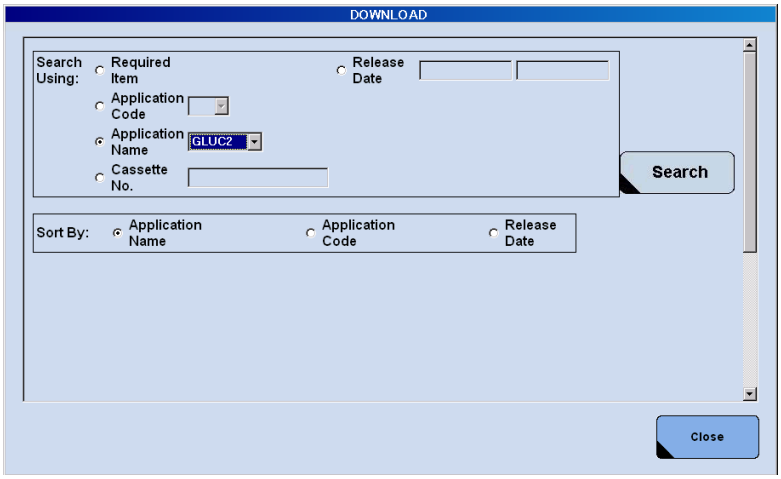


Figure B-124 Download window (application)

3 Select the search condition in the **Search Using** area:

- **Application Code**: Select the application code (ACN) from the list box.

 The application code number (ACN) is available in the instructions for use of the corresponding **cobas c** pack. Up to four applications (ACN) per **cobas c** pack are possible.

 The **Application Code** is the simplest search option for **c** 501 applications.

- **Application Name**: Select the application name from the list box.

 The **Application Name** is the simplest search option for **e** 601 applications. The application name is printed on the **cobas e** pack label.

4 Select **Release Date** in the **Sort By** area to sort the displayed search results by the release date.

5 Choose **Search**. A list of items that meet the given search conditions appears.

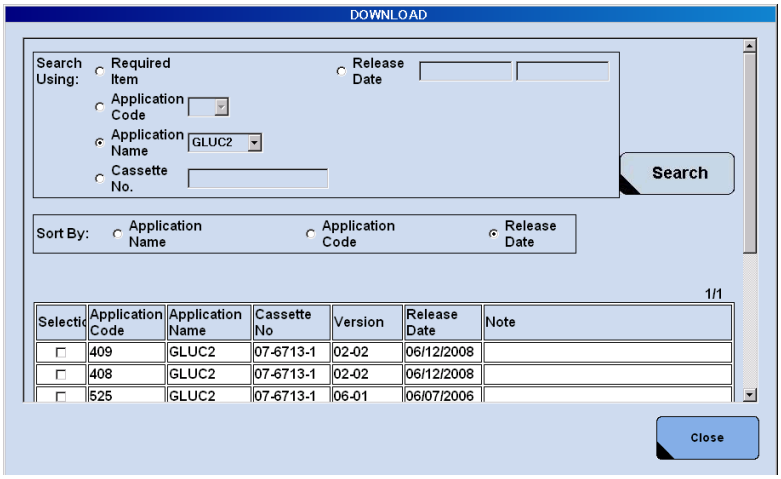


Figure B-125 Download window (application)

In the **Notes** column you can find additional information about the application such as reason for change.

Several search results

If the **Download** window displays several search results, note the following:

- Choose **[Next >]** to display more search results.
- Use the scroll bar on the right side to display the **Download** button.

6 Select the check box of the list item to be downloaded.

Download the data with the latest release date.

7 Choose **Download** and confirm with **OK**.

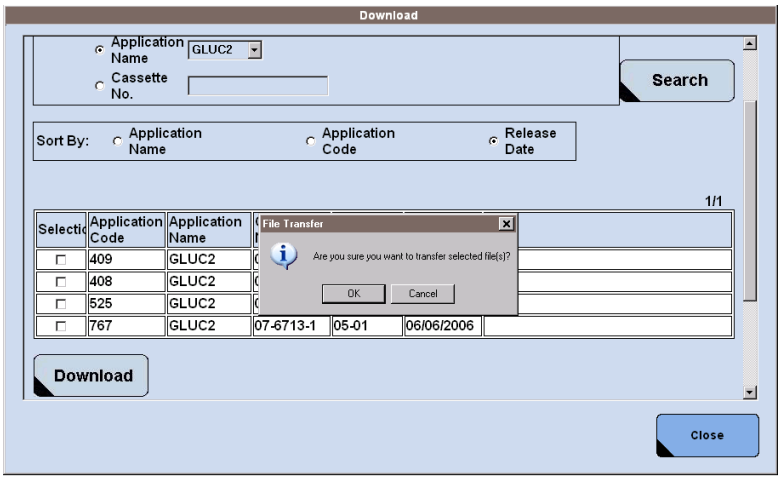
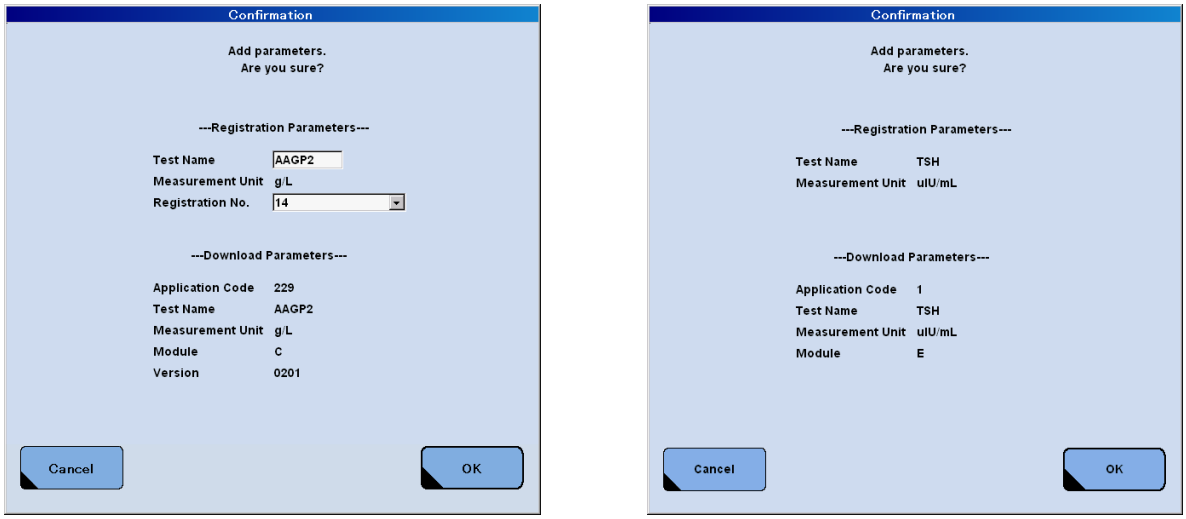


Figure B-126 Download application: File transfer

8 Choose **OK** to confirm the **Confirmation** window.



A Confirmation window **c** 501

B Confirmation window **e** 601

Figure B-127 Download application: Confirmation window

The **Confirmation** window displays the downloaded application data, such as the **Test Name**. It is possible to assign a different test name (up to 5 characters) if needed (**c** 501 application only).

Changing of the Test Name (c 501)

Once the application has been downloaded, the test name cannot be changed. In order to change the test name, the application needs to be deleted and downloaded again.

9 Choose **Close** to return to the **Utility** > **Application** screen. The application parameters of the downloaded application are displayed on the **Application** screen. Some parameters are user-definable.

See *Description of application parameters* on page B-260.

10 To continue the application installation, assign the application to a module.

See *Description of application parameters* on page B-260.

Up to four applications per cobas c pack

Up to four applications per **cobas c** pack are possible on the **cobas** 6000. For example Ca: 706 (10 min) and 726 (STAT 3 min). Install all required applications of a **cobas c** pack before you load the **cobas c** pack on the system.

To install an application for a loaded **cobas c** pack, the **cobas c** pack must be unloaded first. After installation of the additional application, this **cobas c** pack cannot be loaded again. A new **cobas c** pack must be used.

■

Updating an application

When an application is modified by Roche Diagnostics and the application is already installed, the application needs to be updated. If this occurs, you will be informed via **cobas** link.

Update of editable application parameters

If an application's e-barcode is downloaded from **cobas** link while another e-barcode (same or other version) for the same ACN is already present on the system, most of the editable application parameters, including text fields, check boxes, drop down menus and option buttons are not overwritten.

Exceptions:

- For **c** 501 editable parameters in the **Other** tab (**Calibrator Code** and pipetting volumes) and serum index values (**Range** tab) are overwritten.
- For **e** 601 the settings in the **QC Violation** area as well as the values for **Repeat Limit** and **Expected Values** always jump back to default.

There is no indication in the software if the editable parameter originates from the old or new e-barcode or has been manually entered. Therefore check the application parameters after overwriting.

In order to make sure that all application parameters are according to the new application's e-barcode, Roche Diagnostics recommends to delete the current application before downloading the new one. Perform calibration and control before you resume routine operation.

*Updating **c** 501 applications*

To update a **c** 501 application, you must download the newest version of the application parameters from **cobas** link.

To download the newest version of the application parameters, follow the procedure for downloading application parameters.

See *To download application parameters from cobas link* on page B-255.

The following table shows the changes made by modifying a **c** 501 application and how to identify the newest version.

Data	Changed by modifying	Indicate newest version
Application code number (ACN)	Not changed	
Application name	Not changed	
Version	Changed	Highest version number
Release date	Changed	Latest release date

Table B-32 Changes made by modifying a **c** 501 application

After downloading the newest application parameters check, all further application-specific data and settings, for example customized application parameters, assigned calibrator and control data.

If updating of calibration or control data is necessary, you will be informed via **cobas** e-library.

*Updating **e** 601 applications*

To update an **e** 601 application, you must delete the existing application and install the updated application.

To delete an application, refer to **Utility** >**Application** screen. Select the application in question in the **Test** list and choose **Delete**.

To install an updated application, follow the procedure for installing an application.

See *Installing an application* on page B-252.

To verify the change please check for the latest release date.

Description of application parameters

It is possible to change some of the default parameters installed with an application to suit individual laboratory practice. These procedures can be performed by an operator with administrator level password only.

Update of editable application parameters

If an application's e-barcode is downloaded from **cobas** link while another e-barcode (same or other version) for the same ACN is already present on the system, most of the editable application parameters, including text fields, check boxes, drop down menus and option buttons are not overwritten.

Exceptions:

- For **c** 501 editable parameters in the **Other** tab (**Calibrator Code** and pipetting volumes) and serum index values (**Range** tab) are overwritten.
- For **e** 601 the settings in the **QC Violation** area as well as the values for **Repeat Limit** and **Expected Values** always jump back to default.

There is no indication in the software if the editable parameter originates from the old or new e-barcode or has been manually entered. Therefore check the application parameters after overwriting.

In order to make sure that all application parameters are according to the new application's e-barcode, Roche Diagnostics recommends to delete the current application before downloading the new one. Perform calibration and control before you resume routine operation.

For instructions on changing default application parameters, see:
To define application dilution ratios (e 601) on page B-262
To define calibration timeouts on page B-266
To define application duplicate limit (e 601) on page B-264
To define application auto masking on page B-265
To define the unit of measure for an application on page B-269
To define application report name on page B-271
To change technical limit (photometric and ISE tests) on page B-272
To change repeat limit on page B-272
To change qualitative fields on page B-273
To change expected values on page B-274
To change default settings on page B-274

Description of application parameters – Analyze tab

The following sections explain certain settings associated with the **Analyze** tab on **Utility** > **Application** screen. Not all settings are described, but the most important ones are discussed here.

To display this screen choose **Utility** > **Application** > **Analyze**.

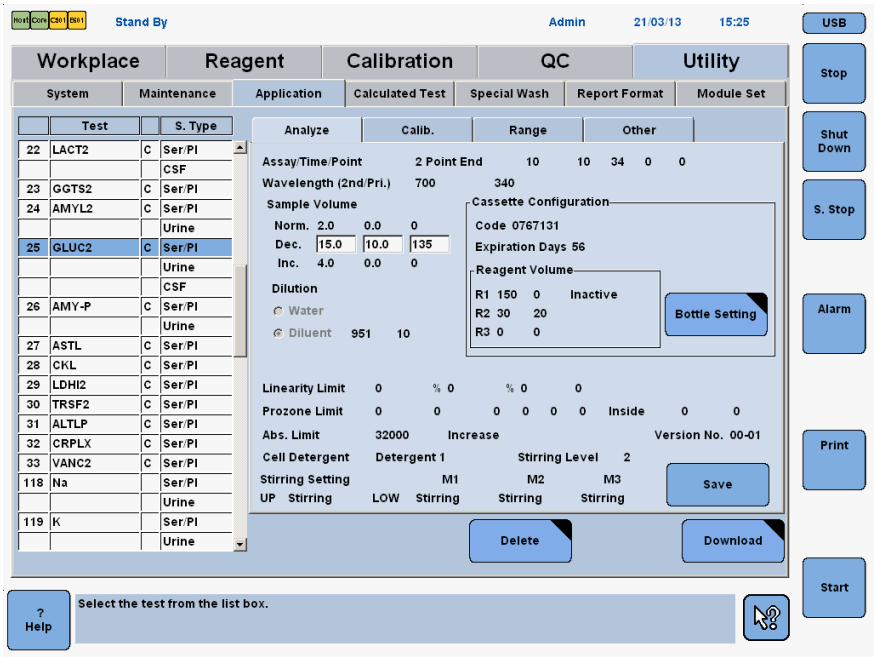


Figure B-128 Analyze tab on Utility > Application screen (photometric tests)

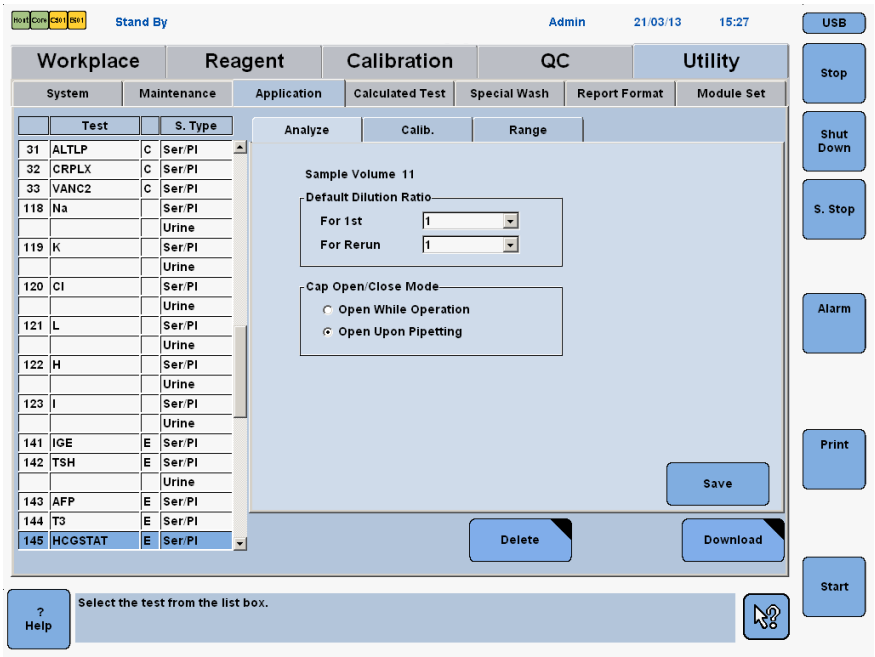


Figure B-129 Analyze tab on Utility > Application screen (immunological tests)

Dilution ratios (e 601)

The **Default Dilution Ratio** area is used to define the dilution ratio for the selected application.

► To define application dilution ratios (e 601)

1 Choose **Utility** > **Application** >**Analyze**.

2 Select the test to be edited from the **Test** list on the left.

3 Select the required dilution for the first run in the **For 1st** list box and for reruns in the **For Rerun** list box of the **Default Dilution Ratio** area.

- A **2** selected from the list box represents a 1:2 dilution.
- A **cobas e** pack must be registered for the test, before the **Default Dilution Ratio** can be entered.

4 Repeat steps 2 and 3 for all necessary tests.

5 Choose **Save** to save the changes made.

■

Description of application parameters – Calib. tab

The following sections explain certain settings associated with the **Calib.** tab on **Utility** > **Application** screen. Not all settings are described, but the most important ones are discussed here.

To display this screen choose **Utility** > **Application** > **Calib**.

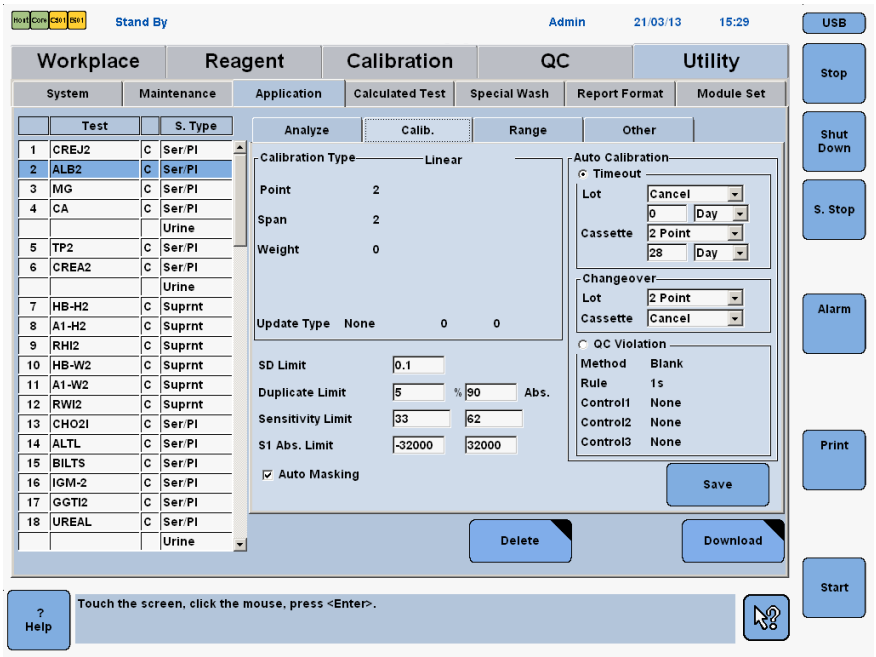


Figure B-130 Calib. tab on Utility > Application screen (Photometric test)

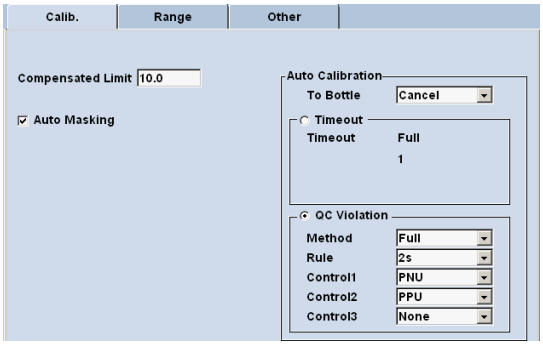


Figure B-131 Calib. tab on Utility > Application screen (ISE test)

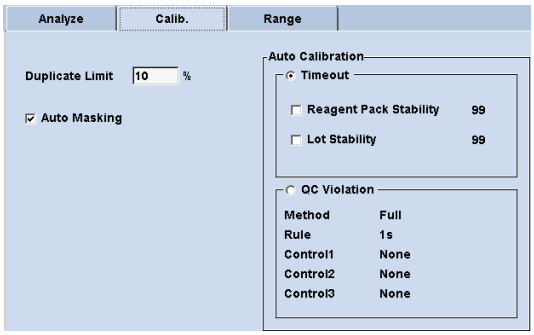


Figure B-132 Calib. tab on Utility > Application screen (Immunological test)

For instructions on changing default application parameters on the **Calib.** tab, see:
To define application auto masking on page B-265
To define calibration timeouts on page B-266
To define application duplicate limit (e 601) on page B-264

Duplicate limit (e 601)

Nearly all Roche Diagnostics **e** 601 calibrators have a default duplicate limit of 10%. This field has a default entry after the download. It is not recommended to change it.

► To define application duplicate limit (e 601)

1. Choose **Utility** > **Application** > **Calib**.
2. Select the test to be edited from the **Test** list on the left.
3. Type the required duplicate limit (0-64), expressed as a percentage (%), in the **Duplication** text box.
4. Repeat steps 2 and 3 for all necessary tests.
5. Choose **Save** to save the changes made.

■

Auto masking

If **Auto Masking** is selected, the particular test requiring calibration due to a failed calibration will be masked automatically.

For more information about calibration masking, see *Calibration concept – masking* on page B-165.

To define application auto masking

1 Choose **Utility** > **Application** > **Calib**.

2 Select the test to be edited from the **Test** list on the left.

3 Check the **Auto Masking** check box to select the test for auto masking.

4 Repeat steps 2 and 3 for all necessary tests.

5 Choose **Save** to save the changes made.

■

To activate the auto masking function, select the **Auto Masking** check box on **Utility** > **System** (**Page 2/4**) > **Calib. Mask Setting**.

Auto calibration

When you load a new application onto the system, the time-triggered calibration (Timeout) is activated by default. If you intend to work with QC-triggered calibration, you must configure the QC violation parameters and activate QC-triggered calibration (**QC Violation**).

For more information, see:
To activate QC violation on page B-265
To define calibration timeouts on page B-266

To activate QC violation

1 On the **Calib.** tab of the **Utility** > **Application** screen select the test to be edited from the **Test** list on the left.

2 Select **QC Violation.**

3 Select the Calibration update **Method** (**Blank**, **Span**, **2 Point**, or **Full**) from the first list box.

4 Select the rule for checking the QC measurement from the **Rule** list.

Calibration will be recommended if a QC result falls out of the specified range (expressed in multiples of one standard deviation).

5 Select the controls that should trigger a calibration.

Up to three controls can be assigned. If any of the QC results falls out of the specified range, a new calibration is recommended.

For each of the assigned controls, an individual confidence interval must be specified. The confidence interval can be calculated automatically using the standard deviation selected in the **Rule** field or it can be entered manually.

For more information, see *Editing control values* on page B-224.

■

Important notes for QC violation:

- At least one control must be selected for Control 1, 2, or 3.
- If a control is deleted, the setting will be changed to None automatically.
- Make sure that at least one control selection for QC violation is other than **None**. Otherwise the QC violation function remains activated if the corresponding radio button is selected but cannot be carried out.
- If calibration is recommended due to QC violation because of control result out of specified range, the control material can be run again. If the controls recur within their confidence limits, the calibration request is removed.

For more information about calibration, see:
Causes for automatic calibration recommendations on page B-156
Calibration concept – c 501 on page B-158
Calibration concept – e 601 on page B-162

► To define calibration timeouts

1 On the **Calib.** tab of the **Utility** > **Application** screen select the test to be edited from the **Test** list on the left.

For e 601 applications:

Before selecting the check box **Timeout** and defining timeout periods, please check the instructions for use. If the check box is not selected, the default values read from the **cobas e** pack barcodes are used (in most cases 7 days for **cobas e** pack stability and 28 days for lot stability).

2 Select **Timeout**.

3 Define the required calibration method and the timeout period:

- For **c** 501 module applications:
 - Select the calibration method for lot calibration from the corresponding list box.
 - Type the required timeout period for lot calibration in the corresponding text box and select the time unit from the corresponding list box.
 - Repeat the last two steps for cassette calibration.
- For ISE applications:
 - Select the calibration method from the corresponding list box.
 - Type the required timeout period for ISE calibration, in days, in the corresponding text box.
- For **e** 601 applications:
 - Select the R**eagent Pack Stability** check box and type the required timeout period for cassette calibration, in days, in the corresponding text box.
 - Select the **Lot Stability** check box and type the required timeout period for lot calibrations, in days, in the corresponding text box.

If you don't want to use timeouts, select both check boxes and enter 0 in the text boxes.

4 Choose **Save** to save the changes made.

■

Description of application parameters – Range tab

The following sections explain certain settings associated with the **Range** tab on **Utility** > **Application** screen. Not all settings are described, but the most important ones are discussed here.

To display this screen choose **Utility** > **Application** > **Range**.

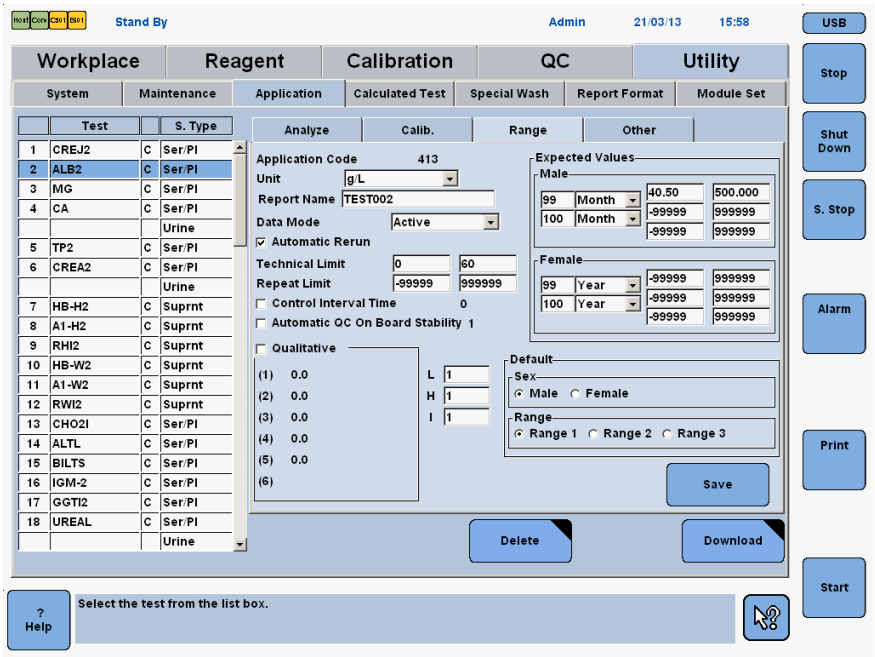


Figure B-133 Range tab on Utility > Application screen (Photometric test)

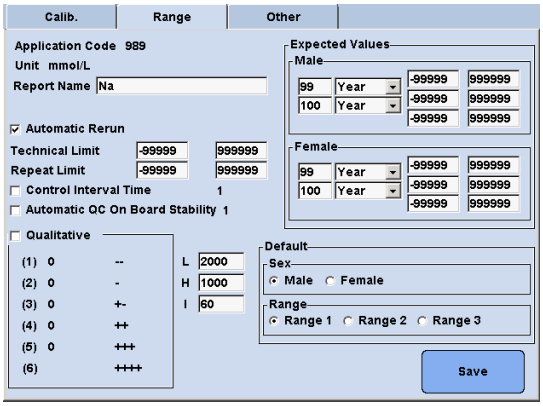


Figure B-134 Range tab on Utility > Application screen (ISE test)

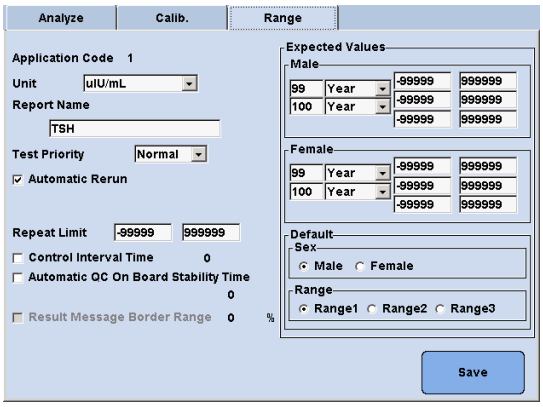


Figure B-135 Range tab on Utility > Application screen (Immunological test)

For instructions on changing default application parameters on the Range tab, see:
To define the unit of measure for an application on page B-269
To define application report name on page B-271
To define application automatic rerun on page B-271
To change technical limit (photometric and ISE tests) on page B-272
To change repeat limit on page B-272
To change qualitative fields on page B-273
To define serum indices on page B-273
To change expected values on page B-274
To change default settings on page B-274

Unit of measure

⚠ CAUTION

Incorrect result due to wrong calibration

You can change the unit of measure after an application has been installed. However, if the unit is changed after the test in question has already been calibrated, we strongly recommend deleting that test application and then reinstalling it.

- After changing the unit of measure, always recalibrate and run controls in order to ensure no incorrect results are reported.

The unit of measure can be selected in this field. Up to four units can be displayed.

The unit of measure can be changed only once by using the drop down list and selecting a different unit. After the unit is changed the field is not a drop down list any more. This can be done after the download of the application or any time later. Be aware, that the system does not recalculate the existing results after the unit is changed.

It is recommended to change the unit of measure directly after download of the application.

► To define the unit of measure for an application

1 On the **Range** tab of the **Utility** > **Application** screen select the test to be edited from the **Test** list on the left.

2 Select the required unit of measure from the **Unit** list box.

3 Choose **Save** to save the changes made.

4 Choose **Yes** to confirm the message of the **Unit Conversion** window.

5 On the **Range** tab of the **Utility** > **Application** screen check the **Technical Limit** against values mentioned the instructions of use

An insignificant difference may be seen between the measuring range values listed in the instructions for use and the value(s) obtained by the instrument after unit conversion. This is caused by the rounding of value(s) during conversion from the unit in the instrument readable data to the unit being used. This may affect the last digit of the value, and has no diagnostic significance.

■

► To change the unit of measure for a previously calibrated c 501 application

1 Backup the database and delete patient data (**System Overview** > **Sample Data Clear** > **Backup and Clear**).

If sample data clear is executed, all the records of the samples are deleted and QC data are moved to the **QC view**.

👁 For details, see *Sample Data Clear button* on page B-44.

2 Unload all the **cobas c** packs for this test (**Reagent** > **Setting** > **Cassette Unloading**).

👁 For details, see *Unloading reagent cassettes* on page B-127.

3 Delete the test application (**Utility** > **Application > Delete**).

4 Reinstall the test application (**Utility** > **Application** > **Download**).

👁 For details, see *Installing an application* on page B-252.

5 Define the unit of measure (**Utility** > **Application** > **Range**).

👁 For details, see *To define the unit of measure for an application* on page B-269.

6 Load new **cobas c** packs.

👁 For details, see *To load a cobas c pack* on page B-49.

7 Install the calibrator values for this test under **Calibration** > **Install** > **Download**.

👁 For details, see *Downloading or updating calibrator data* on page B-184.

8 Check or edit the calibrator concentration values and decimal places under **Calibration** > **Install > Edit.**

👁 For details, see:
Editing calibrator concentrations (c 501) on page B-189
Changing decimal places used for reportable data (c 501) on page B-191

9 Install the control values for this test under **QC** > **Install** > **Download**.

👁 For details, see *Downloading control data* on page B-221.

10 Calibrate the test and perform control measurements.

👁 For details, see *Requesting calibration and QC and printing load lists* on page B-52.

■



cobas c pack unloaded to delete the application have to be discarded, since they will not be accepted by the **c** 501 module again.

► To change the unit of measure for a previously calibrated e 601 application

1 Backup the database and delete patient data (**System Overview** > **Sample Data Clear** > **Backup and Clear**).

If Sample data clear is executed, all the records of the samples are deleted and QC data are moved to the QC view.

For details, see *Sample Data Clear button* on page B-44.

2 Change the unit of measure (**Utility** > **Application** > **Range**).

For details, see *To define the unit of measure for an application* on page B-269.

Changing the unit deletes all QC data

All QC data for the application will be deleted when you change the unit of this application.

■

Report name

This section describes how to define an application report name.

► To define application report name

1 On the **Range** tab of the **Utility** > **Application** screen select the test to be edited from the **Test** list on the left.

2 Type the desired report name for the test in the **Report Name** text box.

3 Choose **Save** to save the changes made.

■

Automatic rerun

This section describes how to define automatic rerun.

► To define application automatic rerun

1 On the **Range** tab of the **Utility** > **Application** screen select the test to be edited from the **Test** list on the left.

2 Select **Automatic Rerun**.

3 Choose **Save** to save the changes made.

■

For more information, see:
Processing reruns on page B-67
Rerun list on page D-63

- If automatic rerun is selected, the sample remains on the rack rotor until the results of the sample are available.
- To perform automatic reruns, the automatic rerun function must be selected (**Start** (global button) > **Automatic Rerun**).

Technical limit (c 501)

► To change technical limit (photometric and ISE tests)

1 On the **Range** tab of the **Utility** > **Application** screen select the test to be edited from the **Test** list on the left.

2 In the first **Technical Limit** box, type the lower limit. In the second box, type the upper limit.

3 Choose **Save** to save the changes.

■

Repeat limit

For each test a clinically relevant range can be typed in here. If the test result is outside this limit but inside the **Technical Limit** of the application, the test is repeated using the same sample volume and dilution as in the first run.

► To change repeat limit

1 On the **Range** tab of the **Utility** > **Application** screen select the test to be edited from the **Test** list on the left.

2 In the first **Repeat Limit** box, type the lower limit of the range. In the second box, type the upper limit of the range.

3 Choose **Save** to save the changes.

■



The concentration range of the **Repeat Limit** must lie within the **Technical Limit**.

For more information, see *Processing reruns* on page B-67.

Control interval time

This check box and the corresponding text box is used to define the time period (1 to 1000 hours) to repeatedly run controls for the selected test. The software checks every 30 minutes whether the set control interval time is exceeded or not. If the interval time is exceeded a QC measurement is automatically requested by the system (Cause: Timeout) or an auto QC measurement is triggered.

See *Automatic QC* on page B-198.

Automatic QC on board stability

This check box and corresponding text box is used to define the on board stability (1 to 1000 hours) for the control material on the rack rotor for the selected test. If Auto QC racks are used and the control material stability expires (On Board stability exceeded), the system displays a yellow alarm. Please refer to the instructions for use of the control to find out the on board stability time.

The analyzer checks every 30 minutes if the on board stability is exceeded or not. In this case the controls have to be taken from the analyzer and be replaced with new ones.

See *Automatic QC* on page B-198.

Qualitative fields (c 501)

This function is important for DAT (drugs of abuse testing). Qualitative reporting can be chosen instead of quantitative reporting for each photometric test. In the text boxes of the first column (1-5) the upper limit concentration range has to be entered. Any result less than or equal to the value defined here will be printed with the text defined in the second box.

If a result is higher than range (5) the text defined in text box (6) is taken.

► To change qualitative fields

1 On the **Range** tab of the **Utility** > **Application** screen select the test to be edited from the **Test** list on the left.

2 Select the **Qualitative** check box to activate the qualitative fields.

3 Type the correct information in the first qualitative text box for (1).

4 Type the symbol that prints on the report in the second text box for (1).

5 Repeat steps 3 to 4 for numbers (2) to (6).

6 Choose **Save** to save the changes.

■

👁 For correct upload setting refer to the Host Interface Manual.

L, H, I (serum index, c 501)

The serum index reference values can be defined individually for each photometric and ISE test. In the serum index fields **L** (lipemic), **H** (hemolytic), **I** (icteric) the ranges that are downloaded with the application are displayed.

Limits for L, H, and I index are implemented in conventional units in all application settings. When using international units for L, H, and I index the respective serum index limits have to be changed in all applications.

If at least one serum index field has a value other than 0, serum indexes are checked. If 0 is entered, the corresponding serum index interference check is not performed.

► To define serum indices

1 On the **Range** tab of the **Utility** > **Application** screen select the test to be edited from the **Test** list on the left.

2 Select the text box of the corresponding serum index **L**, **H**, or **I**.

3 Enter the recommended values from the instructions for use of the corresponding test.

Remember to enter the values in the same unit as those used for the test results (conventional units or international units).

■



To use the serum index function, the serum index application must be installed and the serum index requested on the **Workplace** > **Test Selection** screen.

👁 For more information on serum indices, see *L, H, I (serum index)* on page E-505 or refer to the *COBI-CD*.

Expected values

Expected Values area is used to define the reference ranges for men and women in three different age groups. If a result for this test is outside of the defined ranges, the result receives a H or L flag (only on the printed result).

In the first two text boxes enter an age range in days, months or years. To the right of the age range there are three lines for expected values. In the first line you define the expected values below the age range. In the second line you define the expected values for the specified age range. And in the last line you define the expected values above the age range.

If you don't want to have the H or L flag on the printed result for any of these ranges enter -99999 to 999999.

► To change expected values

1 On the **Range** tab of the **Utility** > **Application** screen select the test to be edited from the **Test** list on the left.

Now, you can change the settings in the **Expected Values** area.

■

► To change expected values ranges and corresponding age

1 In the **Expected Values** area, choose the first text box and enter a patient age for cutoff of the first expected value range. Then select the unit (**Day**, **Month**, **Year**) for that age in the list box.

2 Type the lower and upper reference values for males in the **Male** area in the last 2 text boxes in the row for the specified test.

3 Repeat steps 1 and 2 for the second age cutoff in the second row of text boxes in the **Male** area.

4 In the third row of text boxes, type the lower and upper reference values for males of all ages above the second age cutoff.

5 Repeat steps 1 to 4 for female age cutoff ranges.

Now, you can change the default settings.

■

► To change default settings

1 In the **Default Sex** area, select either the **Male** or **Female** option as the default if no sex is specified.

2 In the **Default Range** area, select the default age range (**Range 1**, **Range 2** or **Range 3**) to be used if no age range is specified.

3 Choose **Save** to save the changes.

■

Description of application parameters – Other tab (c 501)

The following section explains how to set up two independent sets of calibration curves for different sample types for each ISE test Na^+, K^+, and Cl^-.

To display this screen choose **Utility** > **Application** > **Other**.

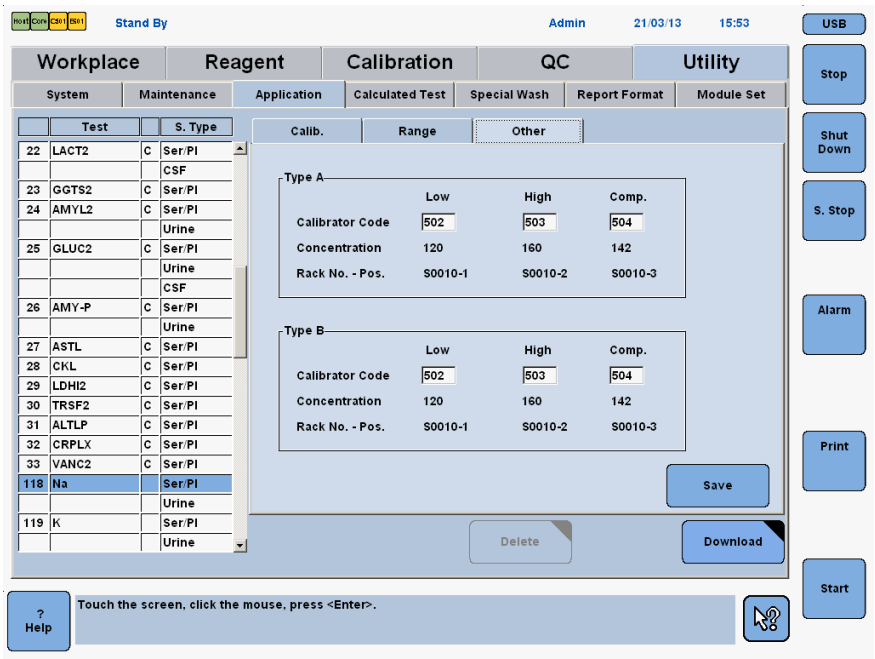


Figure B-136 Other tab on Utility > Application screen (ISE test)

Use the **Other** tab to set up two independent sets of calibration curves for different sample types for each ISE test Na^+, K^+, and Cl^-. Choose an ISE test from the test list to display calibrator codes, concentration values, and rack position numbers.

Setting up individual calibration curves for each ISE sample type

The **Other** tab of the Na, CI and K contains two areas, **Type A** and **Type B**, where each area relates to one of the two independent calibration curves.

To use these calibration curves for a specific sample type, the following settings have to be done:

- Set the calibrators used for generating the calibration curve type A and B.
- Assign an ISE calibration curve for each sample type.

► To set the calibrators for calibration curve type A and B

1 On the **Other** tab of the **Utility** > **Application** screen select the ISE test to be edited from the **Test** list on the left.

2 Enter the codes of the calibrators used for generating the calibration curve type A in the corresponding text boxes for each calibrator, **Low**, **High** and **Comp**.

3 Repeat steps 2 for calibration curve **Type B**.

4 Choose **Save** to save the changes made.

■

If only one calibration type is used—if you use the same calibration curve for all sample types— then you must enter the same calibrator codes for **Type A** and **Type B**. It is not possible to inactivate one of the calibrator curves.

► To assign an ISE calibration curve for each sample type

1 Choose **Utility** > **System** (**Page 3/4**) > **ISE Calib Setting**.

2 Select the calibration curve type (**ISE-A** or **ISE-B**) for each sample type.

3 Choose **OK** to save the changes made.

■

For more information, see:
Calibration concept - ISE applications on page B-159
ISE calibration on page B-193

If a field is grayed out, the field is read only for the password level logged onto the system. At an administrator level, if the field is not grayed out, it can be edited.

System configuration

This section explains how to perform certain tasks associated with the **Utility** > **System** menu.

The entire module set (module configuration, test assignment) should be performed before the other settings (control, calibrator settings)

For more information on configuring the modules, see *Module Set* on page B-287.

To display this screen, choose **Utility** > **System**.

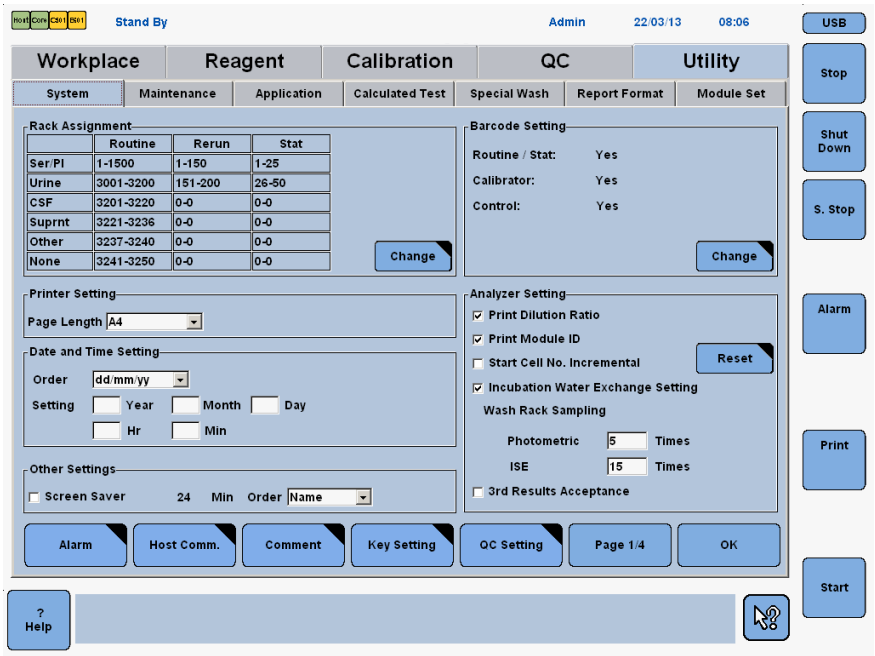


Figure B-137 Utility > System screen

For information about particular tasks associated with this screen, see *Programming system parameters* on page B-278.

Programming system parameters

Many system parameter settings can be customized according to your laboratory's needs. Your Roche service representative programs these according to your specifications during installation.

You can adjust the following system parameter settings.



Backup after programming system parameters

After (re)programming system parameters, it is strongly recommended that you make a backup disk. However, some items cannot be saved to disk.

See *Saving system parameters* on page B-310.

System parameter	screen/window
Assign Rack Numbers	Utility > System
Set the Printer Page Size	Utility > System
Set Date and Time	Utility > System
Set The Screen **Saver**	Utility > System
Order (Name/Test No.)	Utility > System
Set The Barcode Mode	Utility > System
Print Dilution Ratio	Utility > System
Print Module ID	Utility > System
Start Cell No. Incremental	Utility > System
Incubation Water Exchange Setting	Utility > System
Wash Rack Sampling	Utility > System
3rd Results Acceptance[(a)]	Utility > System
Define Alarm Settings	Utility > System (Page 1/4) > Alarm
Define Host Communication Settings	Utility > System (Page 1/4) > Host Comm.
Define Comment Titles	Utility > System (Page 1/4) > Comment
Assign Test Keys	Utility > System (Page 1/4) > Key Setting
Define Test Group Names	Utility > System (Page 1/4) > Key Setting
Add/Edit a Profile	Utility > System (Page 1/4) > Key Setting > Profile Setting
Define QC Settings	Utility > System (Page 1/4) > QC Setting
Activate Host Communication Setting	Start (global button)
Program Default Profiles	Start (global button) > Default Profile
Define Reagent Level Check Alarms	Utility > System (Page 2/4) > Reagent Level
Activate Calibration Mask Settings	Utility > System (Page 2/4) > Calib. Mask Setting
Define Maintenance Settings	Utility > System (Page 2/4) > Maintenance Setting
Define Pipe Settings	Utility > System (Page 2/4) > Pipe Setting
Define Power Up Pipe Settings	Utility > System (Page 2/4) > Power Up Pipe Setting
Assign Operator IDs	Utility > System (Page 3/4) > Operator ID Setting

Table B-33 System parameters (Sheet 1 of 2)

(a) This setting is read in case there is no sample information on the **Data Review** screen.

System parameter	screen/window
Define Check Digit Settings - Barcode Mode	Utility > System (Page 3/4) > Check Digit Setting
Define ISE Calib Setting	Utility > System (Page 3/4) > ISE Calib Setting
Define Rack Delivery Setting	Utility > System (Page 3/4) > Rack Delivery
(and Rack Reception Mode)	
Dilution And Cleaner Cassette Setting	Utility > System (Page 3/4) > Dil. + Cln.
Activate Automatic Printout	Utility > System (Page 4/4) > Automatic Printout
Download Setting	Utility > System (Page 4/4) > Download
Review By Exception	Utility > System (Page 4/4) > Review By Exception
Activate Automatic Rerun	Start (global button)
Set Alarm Sounds	Alarm (global button) > Sound
Application parameter Compensated test parameter Calculated test parameter Manual test masking Carryover evasion setting Maintenance log setting Test assignment setting Scale setting of: • Calibration Trace window • Working Information window • Reaction Monitor window	Read via Utility > Maintenance > Maintenance (Maintenance Type) > Parameter Read/Write

Table B-33 System parameters (Sheet 2 of 2)

(a) This setting is read in case there is no sample information on the **Data Review** screen.

Generating multiple results for a single test

It is always possible to generate 2 results for each test: 1st run and rerun. Select the **3rd Results Acceptance** check box on **Utility** > **System** to expand the ability to generate multiple results for a single test.

Description of 3rd Results Acceptance

When **3rd Results Acceptance** is activated, it is possible to request a test more than two times after confirming a safety warning. Any third or subsequent result will overwrite the previous rerun result.

The repeated rerun is only performed if the previous rerun result has been sent to the Host. In case the previous result is not transmitted prior to the repetition request, the sample is not pipetted.

Preconditions for 3rd Results Acceptance

Before activating **3rd Results Acceptance** it is necessary to check the following conditions.

► To activate 3rd Results Acceptance

1. Choose **Start** (global button) to open the **Start Conditions** window.
2. Verify if in the **Host Setting** area, that the Host communication is enabled. If not, choose **Change**, select the **Communication On** check box, and choose **OK**.

 If Host communication is not available, it is not possible to use **3rd Results Acceptance**.
3. Choose **Workplace** > **Data Review** > **Send To Host** and send all results to the Host. Then delete all data from the database by choosing **Delete All**.
4. Choose **Utility** > **System**.
5. Select the **3rd Results Acceptance** check box in the **Analyzer Setting** area.
6. Choose **OK** and confirm the warning message.

 With this confirmation you allow the system to overwrite rerun results by third and subsequent results.

■

Assigning tests or profiles to test keys

This section describes how to assign tests or profiles to a test key.

► To display the Key Setting window

1 Choose **Key Setting** on **Utility** > **System** (Page 1/4)

■

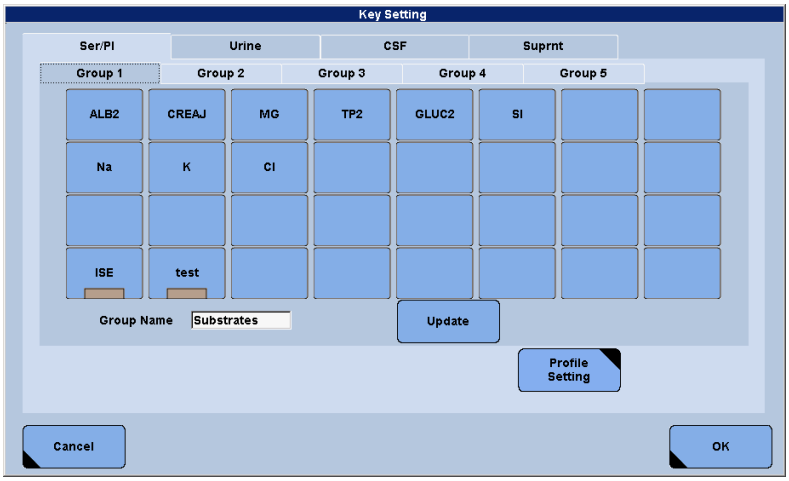


Figure B-138 Key Setting window

This window is used to assign tests or profiles to test keys. One test or profile can be assigned to each test key. Tests can be assigned for up to 5 groups of 32 keys per sample type. In total 160 test keys are available for each sample type.

► To define a group name

1 Choose the sample type tab, for example, Ser/PL

2 Select the **Group** tab (Group 1-5).

3 Type the name of the group in the **Group Name** box.

The group name can be defined individually, for example, hormones, thyroids, tumor marker. The name appears in the selected tab in the **Test Selection** window.

See *Test Selection screen* on page B-80.

■

► To assign a test or a profile to a key

1 Choose **Utility** > **System** (**Page 1/4**) > **Key Setting.**

2 Choose a key on the **Key Setting** window. The available tests and profiles are displayed.

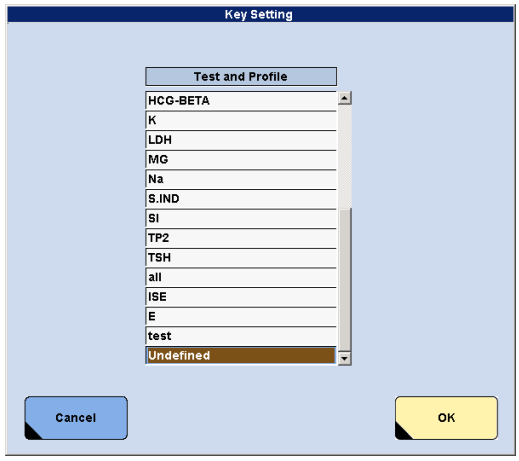


Figure B-139 Key Setting window

3 Select a test or a profile from the list and choose **OK**.

For defining a profile, see *To define a profile* on page B-283.

- If you want to delete a test key assignment, select **Undefined** at the end of the list.
- Only tests and profiles valid for the selected sample type are displayed.

4 Repeat step 2 and 3 to select a key for other tests.

5 Choose **Update** on the **Key setting** window to update the new information.

6 Then choose **OK** to close the window.

■

Key order and pipetting order (e 601)

If you request a sample with **e** 601 tests, the key order in the **Test Selection** screen defines the pipetting order of the tests. It starts from left to right, and from top to button.

If the samples are requested by a host, the host trace defines the pipetting order.

► To define a profile

Profiles are sample type specific, this means the sample type has to be selected.

1 Choose **Utility** > **System** (**Page 1/4**) > **Key Setting** > **Profile Setting.**

2 Choose the tab of a sample type, for example, **Ser/Pl**.

3 Choose **Profile Setting** on the **Key Setting** window. The **Profile Setting** window is displayed.

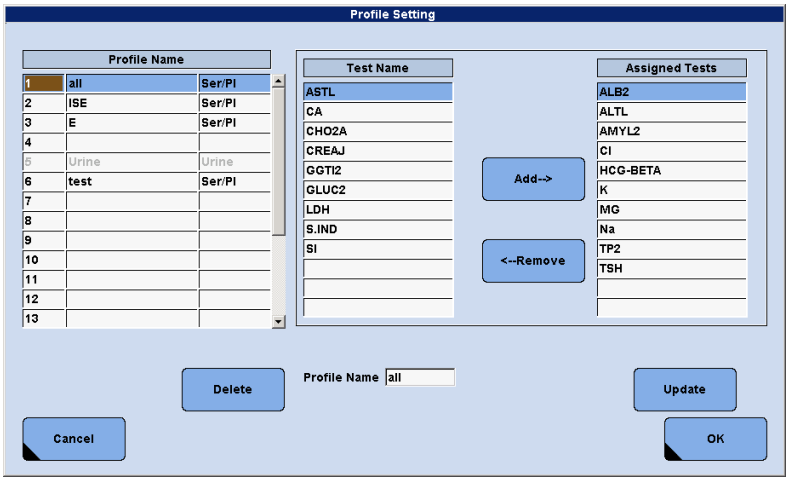


Figure B-140 Profile Setting window

A maximum of 20 profiles in total can be defined in the **Profile Name** list.

4 Select an empty line in the **Profile Name** list.

5 Type in the profile name in the **Profile Name** box.

6 Add the tests that should be included in the profile to the **Assigned Test** list.

When adding the serum index tests, (L, H, I) to a profile, select the **S.IND** test name. Do not add the SI2 or S-SI2 tests to a profile.

7 Choose **Update** to update the information and choose **OK** to save the profile settings.

8 If a profile is assigned to a key, the key on the **Test Selection** screen is marked with a brown bar.

■

Test order in profile and pipetting order (e 601)

If you request a profile with **e** 601 tests, the test order in the profile defines the pipetting order of the tests.

Maintenance / Pipe Setting / Power Up Pipe buttons

Configuration of maintenance related items is described in the corresponding maintenance chapters.

For information, see:
Defining and editing maintenance types on page C-19
Defining and editing maintenance pipes on page C-11
Power Up Pipe function on page C-15

Rack Delivery button

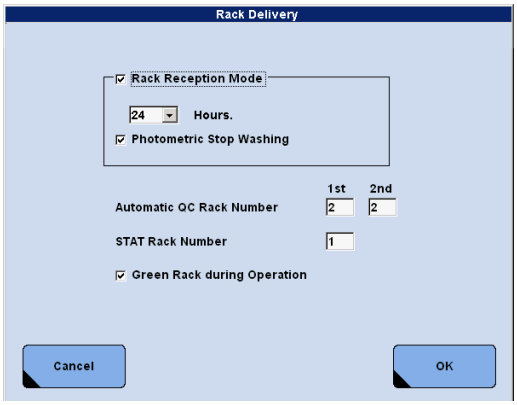


Figure B-141 Rack Delivery window

Use this window to make the following settings:

- Activate or cancel **Rack Reception** mode, set the time period. The following periods are available: **1**, **2**, **4**, **8**, **12** and **24 hours**.
- Activate or cancel **Photometric Stop Washing**.
- Set the number of rack rotor positions that are reserved for automatic QC and STAT racks

 See *Automatic QC* on page B-198.
- Activate or cancel **Green Rack during Operation**.

Rack Reception Mode

Select this check box to activate and configure the rack reception mode (RRM). When the rack reception mode is activated, you can choose this mode on the **Start Conditions** screen.

See *Start Conditions screen* on page E-186.

Use the **Hours** list box to specify the duration of the rack reception mode. The following periods are available: **1**, **2**, **4**, **8**, **12** and **24** hours. The count down for the remaining time starts, when the system changes to operation mode. The remaining time for RRM is shown in the status line.

See *Start Conditions screen* on page E-186.

For an analysis started without RRM, the system automatically turns to Stand By after the last available sample is processed.

For an analysis started with active RRM, the system remains in operation after the last available sample is processed and until one of the following occurs:

Action	Result
Specified time is elapsed	System goes into stand by
S.Stop button is chosen	System goes into stand by
Stop button is chosen	System goes into stand by
A red alarm is issued	System goes into stand by
A wash rack is loaded	The wash rack is processed and then the system goes into stand by (only if **Green Rack during Operation** is not selected)

Table B-34 Stopping the system in rack reception mode

If there are still samples to be processed after the RRM time has elapsed, the system finishes these samples and goes to Stand by afterwards.

If you want to stop the RRM before the specified time is elapsed, proceed as follows:

► To interrupt the Rack Reception mode

1. Choose **Start** (global button).
2. Choose **Change** in the **Rack Reception Mode** area.
3. Clear the R**ack Reception Mode** check box and confirm with **OK**.

 The **Rack Reception Mode** is stopped. The system goes into stand by after all samples in process are finished and the finalization is performed.
4. Choose **Cancel** to close the **Start Conditions** screen.

■

- The remaining time for RRM is shown in the status line.
- Changes to the duration of the rack reception mode can only be done in stand by.
- If an **e** 601 module was in rack reception mode or operation mode for 12 hours or more and has not been returned to stand by, initial bead mixing has to be performed. Initial bead mixing is carried out automatically after the module is started from stand by.
- The system goes into stand by after 24 hours if 24 hours is specified as the duration of the rack reception mode.

*Photometric Stop Washing (**c** 501)*

During operation and rack reception mode the reaction cells of the **c** 501 module are continuously washed. To disable the washing function, select the **Photometric Stop Washing** check box. In this case washing stops, after the last sample is processed.

Cell washing is automatically enabled when the next analysis is started.

This check box is available only if rack reception mode is selected.

Automatic QC Rack number / STAT Rack number

Set the number of slots for each rotor that will be reserved for **Automatic QC** and STAT racks during operation.

The reserved number of slots will be used by the automatic QC or STAT racks. The number of slots reserved for automatic QC should correspond with the specified rack range for automatic QC racks.

Positions for STAT racks in the rack rotor can be defined for the first rack rotor. The reserved rack positions for STAT racks in the second rack rotor cannot be defined. On this rack rotor one rack position is reserved for STAT racks per default.

See *Automatic QC* on page B-198.

At least one position should be reserved for a STAT rack if working with STAT samples

If no position is reserved for a STAT rack and all positions are occupied by other racks, the STAT rack cannot be processed until a rack is removed from the rack rotor.

Number of reserved rack positions

When working **with** automatic rerun reserve a maximum of 5 positions on the rack rotor for Auto QC samples and STAT samples.

When working **without** automatic rerun reserve a maximum of 10 positions on the rack rotor for Auto QC samples and STAT samples.

When working with Auto QC racks reserve at least two positions for Auto QC racks on the second rack rotor.

Green Rack during Operation

⚠ CAUTION

Incorrect results due to wrong calibration

After processing a green wash rack all ISE tests must be calibrated.

- P-mask the ISE before running the green wash rack during operation.

For information about P-masking, see *T-masking and P-masking* on page B-237.

- Do not load samples with ISE requests before you have checked the calibration and QC results for ISE.

Select this check box to activate the **Green Rack during Operation** function. When this function is activated, you can load a green wash rack during operation. The analyzer will not go into stand by after processing of the green wash rack. Therefore a continuous processing of samples is possible.

See *Processing green wash rack* on page C-69.

Module Set

This section explains how to perform certain tasks associated with entire modules rather than specific samples or tests.

Refer to the following procedures to get information about:
Assigning a test to a module on page B-288
Inactivating a module on page B-290

The entire module set (module configuration, test assignment) should be performed before the other settings (control, calibrator settings)

To display this screen, choose **Utility** > **Module Set**.

This screen can be accessed by an operator with administrator level password only.

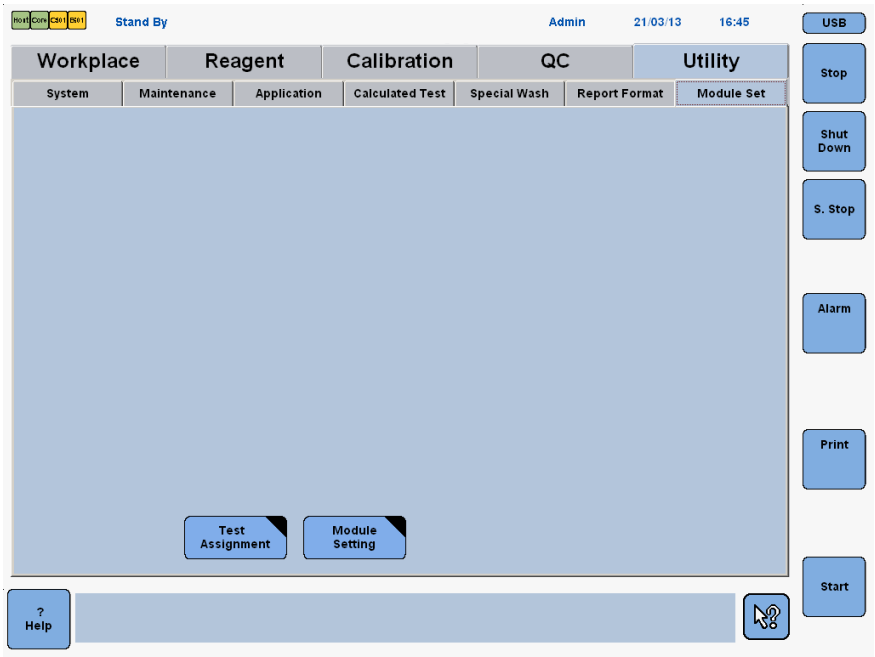


Figure B-142 Utility > Module Set screen

This screen is used to access the **Module Configuration**, **Test Assignment** and **Module Setting** windows

Assigning a test to a module

This section describes how to assign a test to a module.

► To assign a photometric or an ISE test to a c 501 module

1 Choose **Test Assignment** on the **Utility** > **Module Set** screen.

2 Choose the button of the **c** 501 module to which you want to assign the test. The module specific Test Assignment window is displayed.

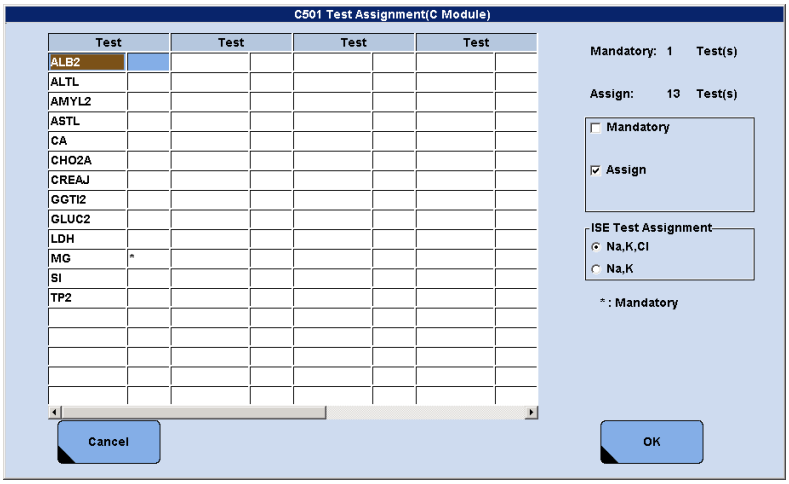


Figure B-143 Test Assignment window – **c** 501

3 Select a test in the **Test** list of the **Test Assignment** window.

4 Select the **Assign** check box.

5 Select the **Mandatory** check box if the reagent has to be on board all the time.

If the **cobas c** pack of a mandatory test is not available on the system, the corresponding module is displayed in red on the **System Overview** screen. Nevertheless operation of the module can start (in contrast to the **e** 601 module).

6 Select **Na, K, Cl** or **Na, K**.

- **Na, K, Cl**: This option allows sodium (Na^+), potassium (K^+) and chloride (Cl^-) ion testing on this ISE module.
- **Na, K**: This option allows only sodium (Na) and potassium (K) testing on this ISE module.

7 Choose **OK**.

■

Installation of an application

For continuing the application installation, download the calibrator data from **cobas** link.

See *Downloading or updating calibrator data* on page B-184.

► To assign a test to an e 601 module

1 Choose **Test Assignment** on the **Utility** > **Module Set** screen.

2 Choose the button of the **e** 601 module to which you want to assign the test. The module specific **Test Assignment** window is displayed.

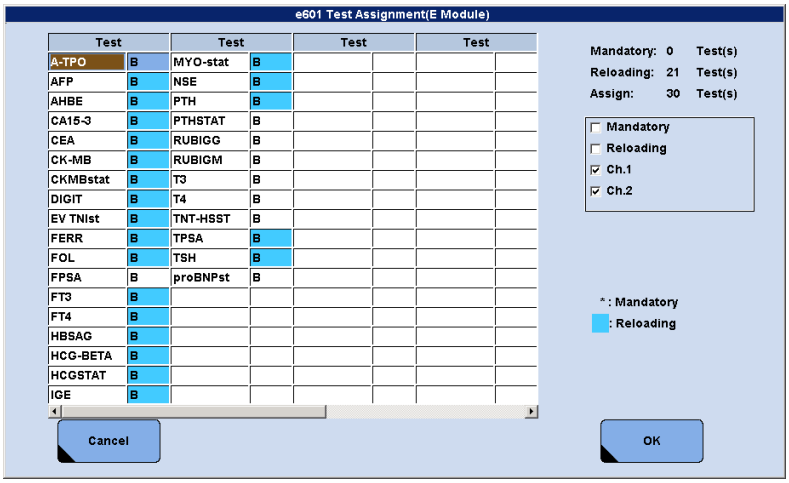


Figure B-144 Test Assignment window – **e** 601

3 Select a test in the **Test** list of the **Test Assignment** window. Check either the **Ch.1**, **Ch.2** or both check boxes to assign the test to measuring channel 1, 2, or both respectively.

A test that is not assigned to any of the channels must not be loaded on the system.

4 Select the **Mandatory** check box if the reagents for the selected test must be available on the module all the time.

If the **cobas e** pack of a mandatory test is not available on the system, the corresponding module is displayed in red on the **System Overview** screen and operation of the analyzer cannot start (in contrast to the **c** 501 module).

5 The **Test** list is updated immediately.

Unassigned tests are grayed out. Tests assigned to an **e** 601 module are followed by a **1**, **2** or **B** indicating they have been assigned to measuring channel 1, 2 or both.

6 Select the **Reloading** check box in order to initiate the reloading process if the selected test runs out of reagent during operation.

For more information, see *Reagent reloading (e 601)* on page B-128.

7 Choose **OK**.

■

Installation of an application

For continuing the application installation, download the calibrator data from **cobas** link.

See *Downloading or updating calibrator data* on page B-184.

Inactivating a module

Use this procedure to inactivate one or more modules. A module cannot perform any automated maintenance functions when it is inactive.

The system must be in stand by to activate or inactivate a module.

► To inactivate a module

1 Choose **Module Setting** on the **Utility** > **Module Set** screen.

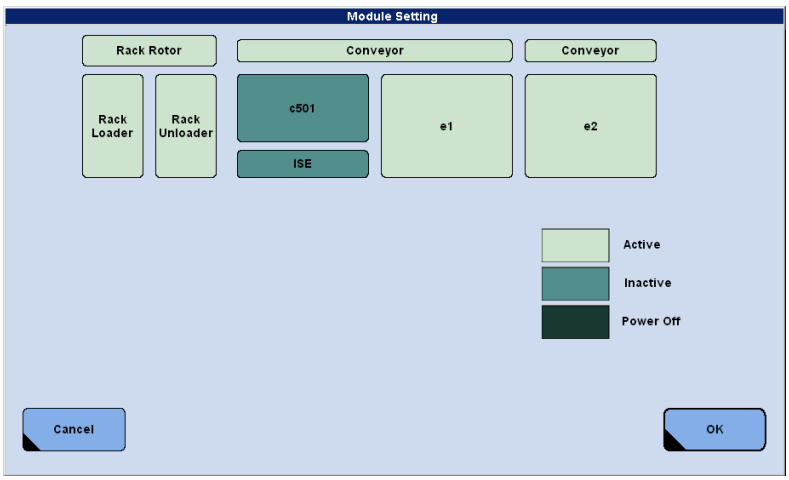


Figure B-145 Module Setting window

This window is used to activate/deactivate or power off modules.

The window displays a system layout diagram from which the module to be activated or deactivated is selected. Choosing a module changes its state successively from active, to inactive, to power OFF, and back. The current status of the module is shown by different colors explained on the window.

2 Choose the appropriate module to toggle between **Active**, **Inactive**, and **Power Off**.

3 Choose **OK** and confirm with **Yes** to apply the assigned settings.

■

If you want to use the **Backup Operation** function, you have to inactivate the rack rotor.

For more information about the **Backup Operation** function, see *Backup operation* on page B-240.

Calculated Tests (c 501)

This section explains how to program calculated tests and compensated tests.

Calculated tests and compensated tests can be programmed for **c** 501 tests only.

To display this screen choose **Utility** > **Calculated Test**.

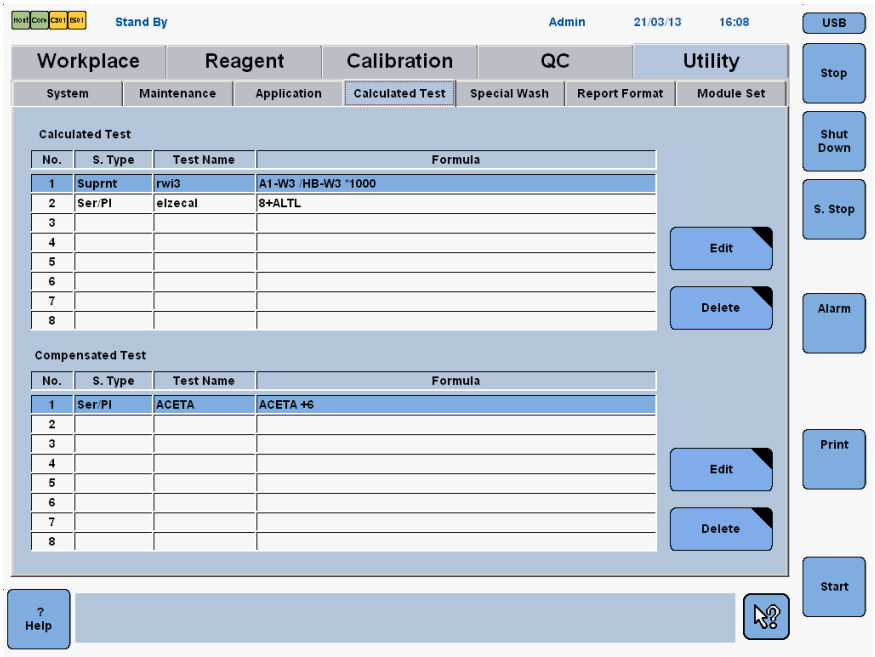


Figure B-146 Calculated Test screen

Programming calculated tests

Calculated test results are not performed on the system but are derived from applying a test formula to the results of clinical chemistry tests performed on the system.

Display of calculated test results

If the conditions for a calculated test are fulfilled, then an additional result is displayed for this sample in the test results list of the **Data Review** screen. The **Test** name for the calculated test in the test results list is the short name defined in the **Item** box. If test data to be used in the calculation is unavailable, the program does not perform the calculation.

In contrast to this the compensated tests overwrites an available result for sample.

Editing of calculated test results

Calculated test results cannot be edited.

QC of calculated tests

A calculated test will be automatically added to the installed controls in **QC** > **Install** screen. The QC result for the calculated test is visible on the **QC** > **Individual** screen and **Individual QC Chart**.

For more information, see:
QC Install screen on page B-220
QC Individual screen on page B-209

Real Time QC and **QC Run Status** is not available for calculated tests.

► To program a calculated test and enter a calculated test formula

1 Choose **Utility** > **Calculated Test**.

2 Select an empty line from the **Calculated Test** list at the top of the screen.

3 Choose **Edit**. The **Calculated Test Formula** window is displayed.

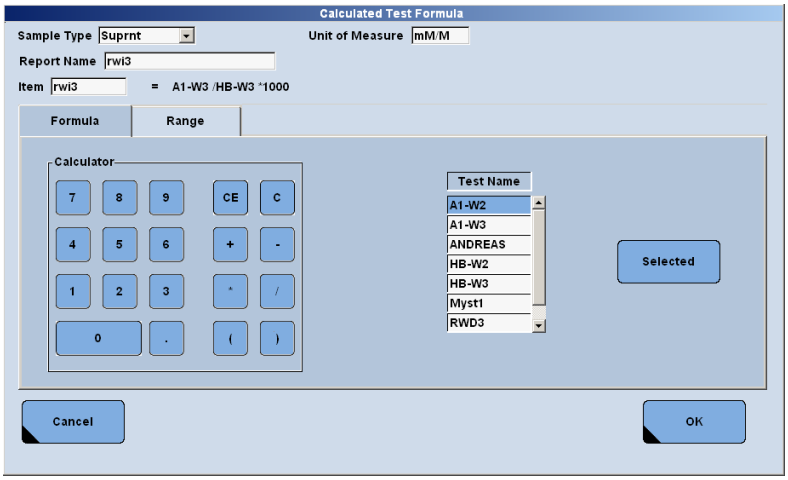


Figure B-147 Calculated Test Formula window

4 Select the type of sample (**Ser/Pl**, **Urine**, **CSF**, **Suprnt**) for which the calculated test formula is being created from the **Sample Type** list.

5 Type the unit of measure in the **Unit of Measure** box.

6 Type a name for the calculated test as it should appear on the report in the **Report Name** box.

7 Type the short name of the calculated test in the **Item** box.

Only alphabetic and numerical characters can be used.

8 Enter the formula (the formula appears to the right of the **Item** text box, after the equal sign):

- To add a test to the formula, select the test that is part of the formula from the **Test Name** list and choose **Selected**.
- To add mathematical operators and numerals, use the **Calculator** area in the window to enter these in the correct sequence along with test names until the formula is complete.

9 Now, set the range parameters.

■

► To set range parameters

1 Choose the **Range** tab.

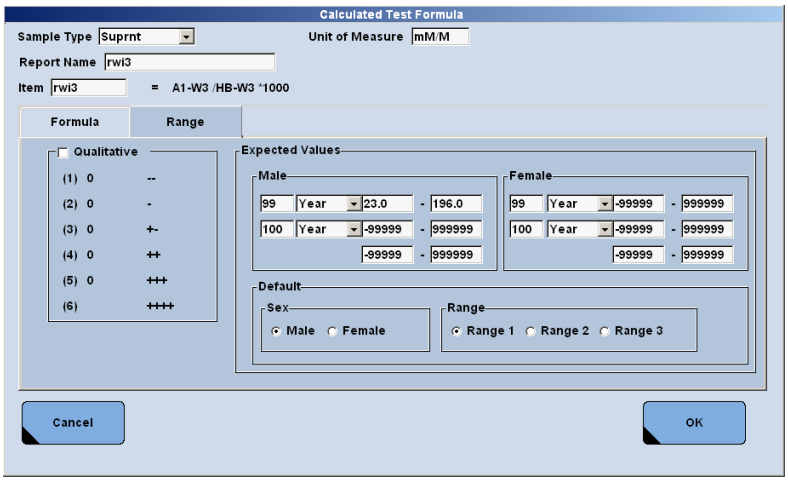


Figure B-148 Calculated Test Formula - Range tab

2 Type the expected value ranges or the qualitative parameters in the **Range** area, if needed. Select the **Default** setting, if needed.

3 Choose **OK** to save the new formula and close the **Calculated Test Formula** window. The new formula is shown in the **Calculated Test** list box at the top of the **Calculated Test** screen.

The number of digits displayed to the right of the decimal in the calculated test result is determined by the number of digits entered to the right of the decimal for the first Male Expected Value field on the **Range** tab of the **Calculated Test Formula** window.

4 Choose **Utility** > **Report Format**.

5 Select the defined test in the **Print Order** area.

6 Type an unused line number into the **Line** field.

7 Choose **Update** and **Save** to save the changes.

■

► To edit a calculated test formula



If a calculated test formula is edited, the calculated test result displayed on **Data Review** is modified.

1. Choose **Utility** > **Calculated Test**.
2. Select the calculated test formula to be edited from the **Calculated Test** list box at the top of the screen.
3. Choose **Edit** to display the **Calculated Test Formula** window.
4. Use **C** in the **Calculator** area of the window to clear the entire formula or **CE** to clear components of the formula one at a time from right to left.
5. Enter the formula (the formula appears to the right of the **Item** text box, after the equal sign):
 - To add a test to the formula, select the test that is part of the formula from the **Test Name** list and choose **Selected**.
 - To add mathematical operators and numerals, use the **Calculator** area in the window to enter these in the correct sequence along with test names until the formula is complete.
6. Choose the **Range** tab. Type the expected value ranges or the qualitative parameters in the **Range** area, if needed. Change the **Default** settings, if needed.
7. Choose **OK** to save the formula programming and close the **Calculated Test Formula** window. The revised formula appears in the **Calculated Test** list box at the top of the **Calculated Test** screen.

■

► To delete a calculated test formula

1. Choose **Utility** > **Calculated Test.**
2. In the **Calculated Test** list box, select the calculated test to be deleted.
3. Choose **Delete** to the right of the **Calculated Test** list box. A confirmation window appears.
4. Choose **Yes** to delete the calculated test and close the window.

■

Programming compensated tests

Clinical chemistry test results can be processed on the system and adjusted by applying a compensated test formula. Use the following procedures to add, edit or delete a compensated test formula.

► To enter a compensated test formula

1 Choose **Utility** > **Calculated Test**.

2 Select an empty line in the **Compensated Test** list box at the bottom of the screen.

3 Choose **Edit** to display the **Compensated Test Formula** window.

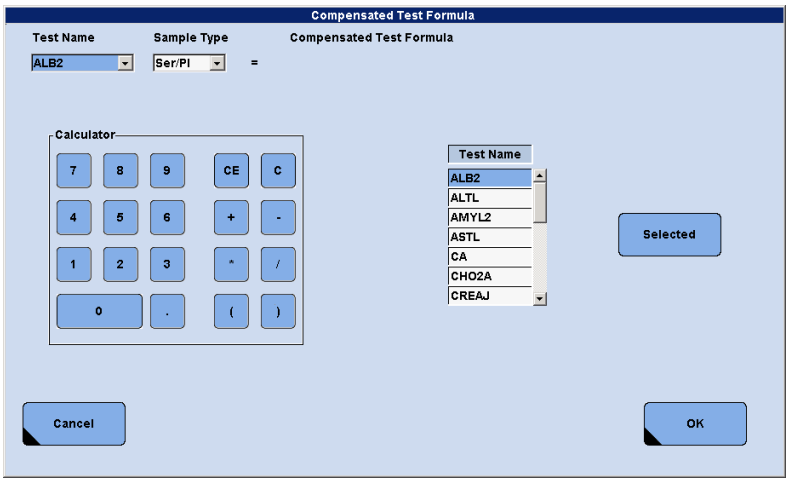


Figure B-149 Compensated Test Formula window

4 Select the test and sample type to be compensated from the **Test Name/Sample Type** list box in the upper left corner of the window.

5 Enter the formula (the formula appears to the right of the **Sample Type** list box, after the equal sign):

- To add a test to the formula, select the test that is part of the formula from the **Test Name** list and choose **Selected**.
- To add mathematical operators and numerals, use the **Calculator** area in the window to enter these in the correct sequence along with test names until the formula is complete.

6 Choose **OK** to save the new formula and close the **Compensated Test Formula** window. The new formula is shown in the **Compensated Test** list box at the bottom of the **Calculated Test** screen.

■

► To edit a compensated test formula

1. Choose **Utility** > **Calculated Test**.
2. Select the compensated test formula to be edited from the **Compensated Test** list.
3. Choose **Edit** to display the **Compensated Test Formula** window.
4. Choose **C** in the **Calculator** area of the window to clear the entire formula, or **CE** to clear components of the formula, one at a time, from right to left. Use the **Test Name** list to select any test that is part of the formula. Choose **Select** after selecting the test to add it to the formula, which is shown at the top of the window. Use the **Calculator** area to enter mathematical operators and numerals in the correct sequence with test names.
5. Choose **OK** to save the formula programming and close the **Compensated Test Formula** window. The revised formula appears in the **Compensated Test** list box at the bottom of the **Calculated Test** screen.

■

Even if a compensated test formula is edited, the already calculated test result displayed on **Data Review** is not modified.

► To delete a compensated test formula

1. Choose **Utility** > **Calculated Test**.
2. Select the compensated test formula to be deleted from the **Compensated Test** list.
3. Choose **Delete**. A confirmation window is displayed.
4. Choose **Yes** to delete the compensated test and close the window.

■

Special Wash

The **cobas** 6000 analyzer series is a random access system. Therefore, reagent probes and reaction cells may cause carryover and thus interferences between tests, and the sample probe may cause sample carryover.

To avoid carryover and cross-contamination between tests use the special wash function. This function allows you to preset combinations of reagents or samples that may cause carryover so that washing will be carried out between them when the combination is encountered during analysis.

The following sections explain how to set the carryover avoiding function:
Programming a special wash for c 501 modules on page B-297
Programming a special wash for e 601 modules on page B-304

Programming a special wash for c 501 modules

Reagent probe, sample probe or cell washes may be required due to potential interference from other reagents or samples. These special washes maintain reagent and sample integrity.

A current carryover prevention list is available on **cobas** link. Refer to the instructions for use for NaOH-D / SMS / Sample Cleaner 1 or 2 / SCCS.

Reagent probe wash

The reagent probes dip into the reagents when aspirating. To evade a reagent carryover, program a special wash cycle for the reagent probe.

► To program a reagent probe wash

1 Choose **Utility** > **Special Wash** > **Chemistry**.

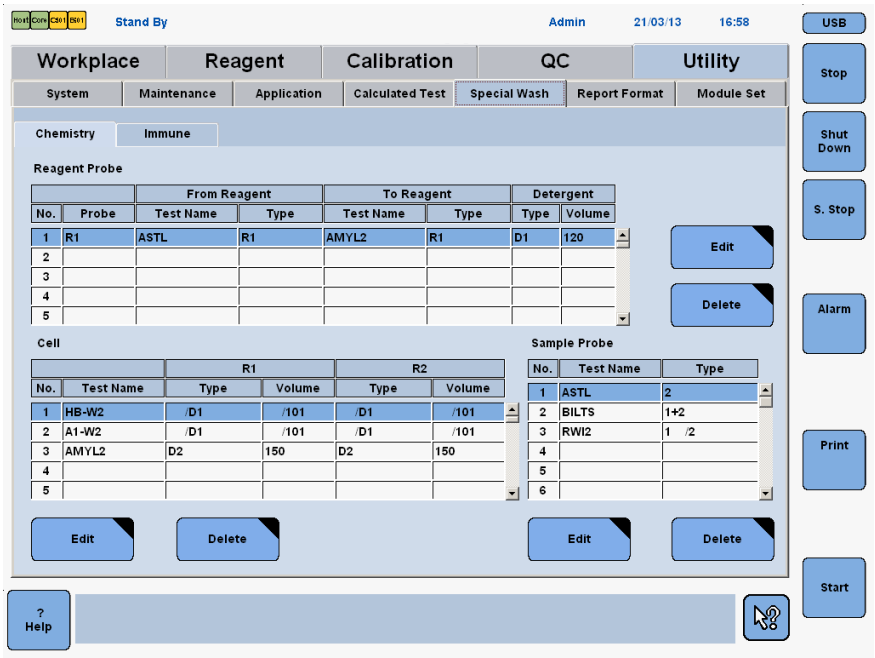


Figure B-150 Special Wash > Chemistry tab

2 Select an empty line in the **Reagent Probe** list to add a reagent probe wash. To edit an existing reagent probe wash, select the corresponding line

3 Choose **Edit**, on the right of the **Reagent Probe** area, to display the **Edit Reagent Probe Wash** window.

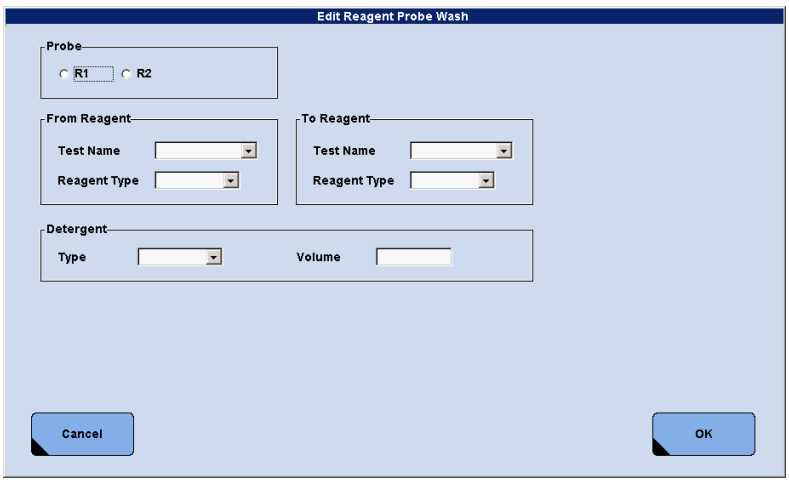


Figure B-151 Edit Reagent Probe Wash window

4 In the **Probe** area, choose **R1** or **R2** to designate which reagent probe is to be washed.

5 In the **From Reagent** area you have to make the settings for the test from which contamination could be carried over to another test.

- Select the name of the test from the **Test Name** list box. If you select **All Items**, the reagent probe is always washed if the selected test in the **To Reagent** area is pipetted afterwards.
- Select the appropriate reagent type (**R1**, **R2**, or **R3**) in the **Reagent Type** list box.



Individual wash steps must be programmed before the **all tests** wash steps.

6 In the **To Reagent** area you have to make the settings for the test to which contamination could be carried over from another test.

- Select the name of the test from the **Test Name** list box. If you select **All Items**, the reagent probe is always washed if the selected test in the **From Reagent** area was pipetted before.
- Select the appropriate reagent type (**R1**, **R2**, or **R3**) in the **Reagent Type** list box.

7 In the **Detergent Type** list box select the detergent used for washing.

These solutions are used for washing the reagent probe of the **c** 501module.

- D1 (NaOH-D)
- D2 (SMS)
- D3 (SCCS)
- Water

8 Then type the wash solution volume (from 20 to 180 µL) in the **Volume** text box.

9 Choose **OK** to add the new special wash to the list on the **Special Wash** screen and close the window.

10 Check the amount of the appropriate detergent cassette on the instrument on the **Reagent** > **Status** screen

■

► To delete a reagent probe wash

1 Choose **Utility** > **Special Wash** > **Chemistry**.

2 Select the line in the **Reagent Probe** list to be deleted.

3 Choose **Delete** located on the right of the **Reagent Probe** area to delete the reagent probe wash after confirmation.

■

Cell wash

To evade the carryover of traces of the test mixture of one test to the next test measured in that same reaction cell, program a special wash cycle for the reaction cell. In this case a special wash is carried out *before* the corresponding test is performed.

For the HbA1c application (HB-W3, A1-W3) this window shows the **After Sampling** area additionally. In this area you can define special washes for the reaction cell in which the HB-W3 test or the A1-W3 test was performed. In this case a special wash is carried out *after* the corresponding test was performed.

► To program a cell wash

1 Choose **Utility** > **Special Wash** > **Chemistry**.

2 Select an empty line in the **Cell** list to add a cell wash. To edit an existing cell wash, select the corresponding line.

3 Choose **Edit** located below the **Cell** area to display the **Edit Cell Wash** window.

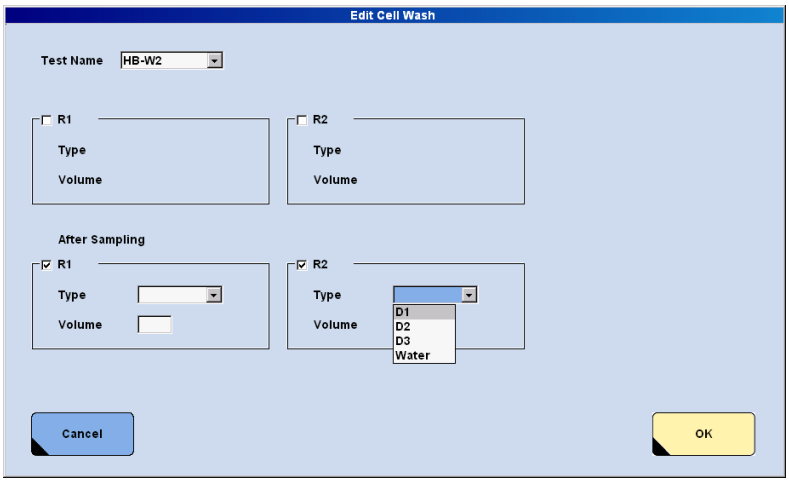


Figure B-152 Edit Cell Wash window

4 Select a test from the **Test Name** list box that may cause carryover.

5 Designate the reagent probe(s) (**R1** or **R2**) that will dispense the detergent by choosing the **R1** and/or **R2** check boxes.

6 In the **Type** list box select the detergent used for washing.

These solutions are used for washing the cells of the **c** 501module.

- D1 (NaOH-D)
- D2 (SMS)
- D3 (SCCS)
- Water

7 Type the cell wash solution volume (from 20 to 180 µL) in the **Volume** text box for each reagent probe selected.



After Sampling area

For the HbA1c application this window shows the **After Sampling** area additionally. In this area you can define special washes for the hemolysate reaction cell. In this case a special wash is carried out after the corresponding test was performed.

8 Choose **OK** to save the settings, add the programming to the **Cell** list box and close the window.

9 Check the amount of the appropriate detergent cassette on the instrument on the **Reagent** > **Status** screen.

■

► To delete a cell wash

1 Choose **Utility** > **Special Wash** > **Chemistry.**

2 Select the test to be deleted from the **Cell** list.

3 Choose **Delete** located below the **Cell** list box to delete the cell wash after confirmation.

■

Sample probe wash

The sample probe dips into the sample when it aspirates sample liquid. To evade a carryover of sample liquid into a test that is sensitive for sample residual, program a special wash cycle for the sample probe.

► To program sample probe wash

1 Choose **Utility** > **Special Wash** > **Chemistry**.

2 Select an empty line in the **Sample Probe** list to add a sample probe wash. To edit an existing sample probe wash, select the corresponding line.

3 Choose **Edit** located below the **Sample Probe** area to display the **Edit Sample Probe Wash** window.

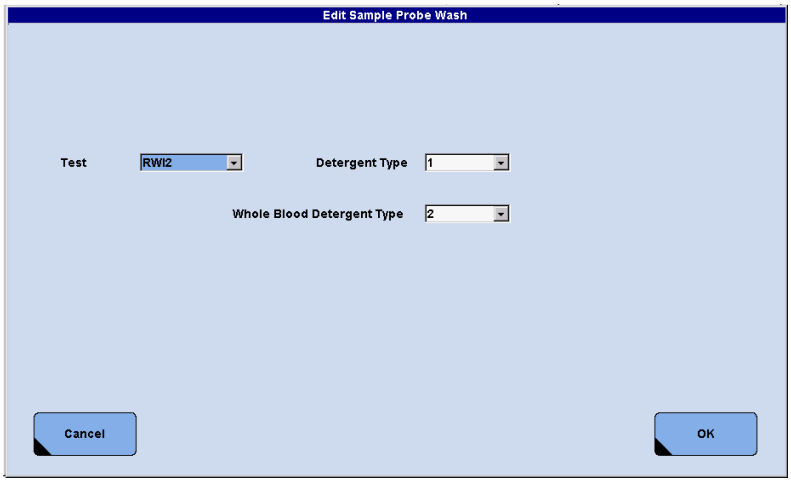


Figure B-153 Edit Sample Probe Wash window

4 Select a test from the **Test** list box that is sensitive for sample residual.

5 In the **Detergent Type** list box select the detergent used for washing.

These solutions are used for washing the sample probe of the **c** 501module.

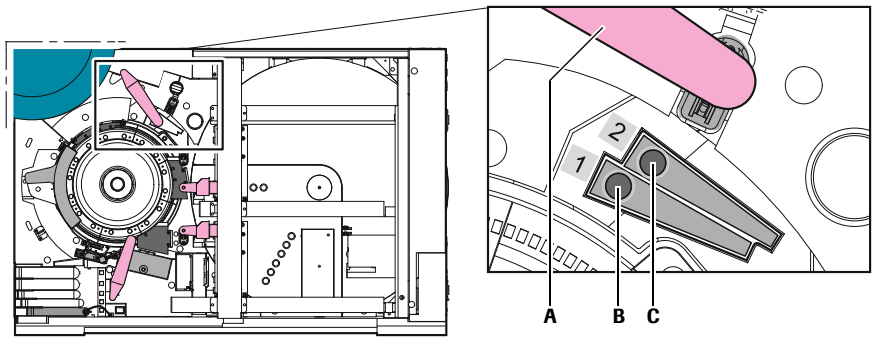
- 1 (Sample Cleaner 1)
- 2 (Sample Cleaner 2)
- 1+2 (Sample Cleaner 1 + Sample Cleaner 2)
- Water

The detergent aspiration volume is 45 µl

6 Choose **OK** to save the settings.

When a sample probe wash is performed prior to sample aspiration for a sample, a *b* appears in the status column on **Workplace** > **Data Review**. The solutions used to clean the sample probe are listed in the **Carryover Evasion** field on the **Workplace** > **Data Review** > **Test Review** screen.

7 Check that the appropriate wash solution is placed on the instrument in the correct position.



A Sample Probe **B** (1) Sample Cleaner 1 **C** (2) Sample Cleaner 2

Figure B-154 Sample probe cleaners

8 Check the amount of the appropriate detergent on the **Reagent** > **Status** screen.

■

► To delete a sample probe wash

1 Choose **Utility** > **Special Wash** > **Chemistry**.

2 Select the test to be deleted from the **Sample Probe** list.

3 Choose **Delete** located below the **Sample Probe** list to delete the sample probe wash after confirmation.

■

Programming a special wash for e 601 modules

Use special wash programs for the **e** 601 reagent probe to avoid potential carryover of reagents to other assays. Special washes maintain reagent and sample integrity.

Reagent probe wash

Heterogeneous immunoassays are very sensitive tests. Some combinations of these assays are especially sensitive against carryover within the **e** 601 module. To prevent such carryover, program a special wash cycle of the reagent probe.

► To program a reagent probe wash

1 Choose **Utility** > **Special Wash** > **Immune**.

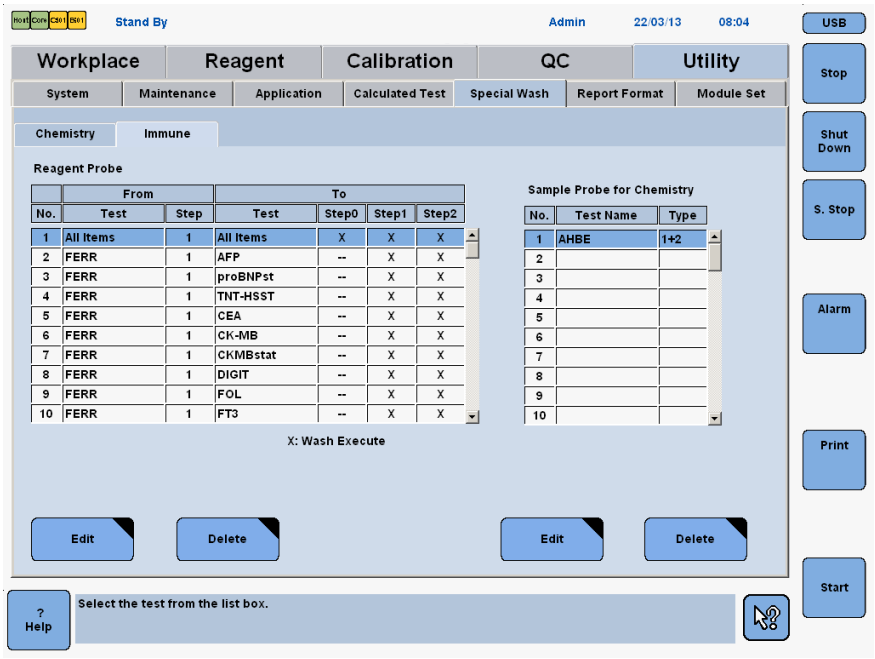


Figure B-155 Special Wash > Immune tab

2 Select an empty line in the **Reagent Probe** list to add a reagent probe wash. To edit an existing reagent probe wash, select the corresponding line.

3 Choose **Edit** located below the **Reagent Probe** area to display the **Edit Reagent Probe Wash** window.

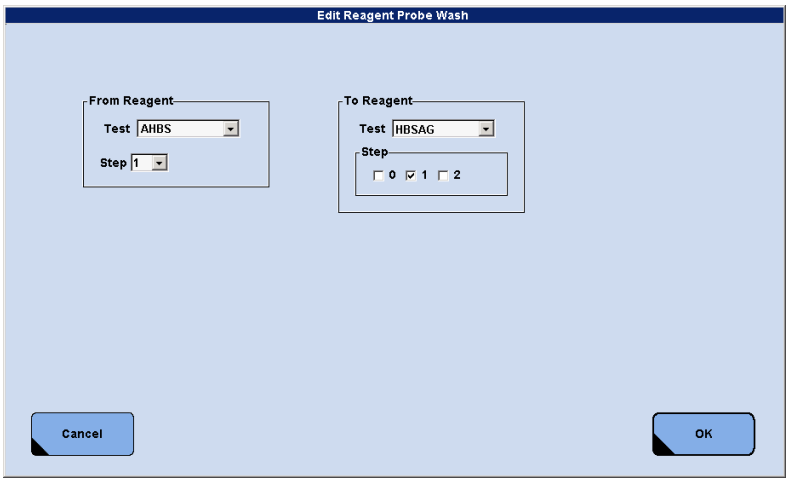


Figure B-156 Edit Reagent Probe Wash window

4 In the **From Reagent** area you have to make the settings for the test from which contamination could be carried over to another test.

- Select the name of the test from the **Test** list box. If you select **All Items**, the reagent probe is always washed if the selected test in the **To Reagent** area is pipetted afterwards.
- Select the pipetting step (**0**, **1** or **2**) from the **Step** list box.
 - Step 0 is used for pretreatment or diluent.
 - Step 1 is the pipetting step before the first incubation.
 - Step 2 is the pipetting step before the second incubation.

5 In the **To Reagent** area you have to make the settings for the test to which contamination could be carried over from another test.

- Select the name of the test from the **Test** list box. If you select **All Items**, the reagent probe is always washed if the selected test in the **From Reagent** area was pipetted before.
- Select which pipetting steps are affected (**0**, **1** or **2**) from the **Step** check boxes.

6 Choose **OK** to save any changes made.

■

Sample probe wash

In the context of **e** 601 special wash, the term *sample probe* refers to the sample probe of the **c** 501, not to the **e** 601 sample probe.

Prior to pipetting the **c** 501 test, the sample probe of the **c** 501 is washed with the specified detergent if afterwards the **e** 601 test (specified on the **Edit Sample Carry Over Evasion** window) is requested.

If a sample has been processed on **c** 501 before an **e** 601 assay is performed and a special wash for the sample probe of the **c** 501 has been performed, a b-flag is added to the result on the **Data Review** screen.

For more information on programming a sample probe wash, see *To program sample probe wash* on page B-302.

Report Format

This section explains how to customize the report format of the patient report.

The patient report (**Print** (global button)> **Work Place**> **Data Monitor/Report**) can be printed in two formats: **Monitor** format or **Report** format. Only the **Report** format can be customized.

Customizing patient report format

This section describes how to customize the patient report format.

► To customize patient report format

1 Choose **Utility** > **Report Format**.

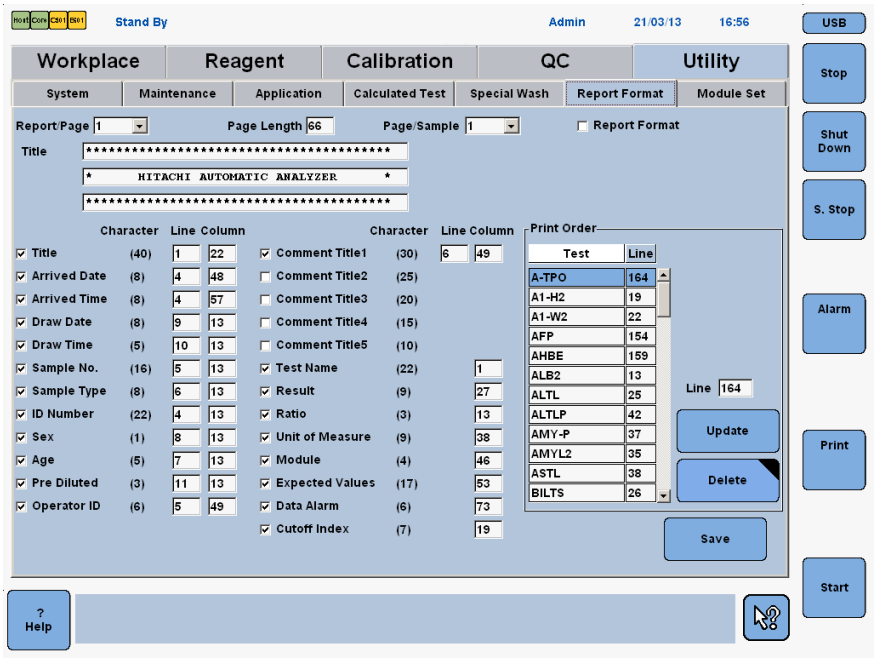


Figure B-157 Report Format screen

Customizing the report format of the patient report consists of the following steps:

- Choose the page layout.
 To choose the page layout on page B-307
- Define the title, the positions of all other items, and the print order.
 To define the title and the positions of all other items on page B-307
- Choose **Save** to save the changes.

■

► To choose the page layout

1 Select the number of reports per page (**1** or **2**) from the **Report/Page** list.

2 Type the page length in lines in the **Page Length** box.

- for US letter (8 1/2 " x 11") type 66
- for A4 (21cm x 29.7 cm) type 72

3 Select the number of pages per sample (**1** or **2**) from the **Page/Sample** list.

4 Select the **Report Format** check box to print patient reports in report format or deselect it to print in monitor format.

If automatic printout is activated (**Utility** > **System** (Page 4/4) > **Automatic Printout**) the patient report (only STAT samples) is printed in the selected format (report format or monitor format).

If you print the patient report from the **Data Monitor/Report** screen (**Print** (global button)> **Work Place**> **Data Monitor/Report**) you can select the format regardless of the setting on the **Report Format** screen.

Results with exception data alarms (**Utility** > **System** (**Page 4/4**) > **Review By Exception**) are not printed in the report format.

For information on exception data alarms, see *Review By Exception window* on page E-419.

■

► To define the title and the positions of all other items

1 Type the title to be used for the report header (up to 3 lines of 40 characters each) in the **Title** text boxes.

2 Assign a print line and column to each of the items of report information, as appropriate.

■

When assigning a print column, allow for the maximum character length for the item if assigning more than one demographic item to a line. For example, if the arrived date is assigned to line 4, column 47 and the arrived time is also assigned to line 4, it must be assigned to column 56 or higher since the character length for the arrived date is 8. If the second item is assigned to a column that is used by the first item, one of the items does not print or only partially prints.

► To alter the print order

Results may not be displayed

If no print order is defined, the result is not printed out or displayed in the **Print/View** screen, although the test itself is measured. If a print order is assigned to a line already used, the result may be overwritten by the other information.

- For each test, a print order number has to be defined.
- The setting of print order corresponds to the test order in the printout. Ensure that print order lines are not used from the information fields.

1 In the **Print Order** area, select the test from the list.

2 Type the line number on which the test is to print in the **Line** text box.

Results may not be displayed

Do not assign the same print line number to a test that is assigned to any demographic information in step 1 from To define the title and the positions of all other items.

3 Choose **Update** to update the print order information.

4 Choose **Save** to save the changes.

■

To check the report setup, print a report example from **Print** (global button) > **Utility** > **Report Example**.

Comparison of data monitor format and report format

This section compares the data monitor format with the report format.

Data Monitor/Report (monitor format)

```
                                  Data Monitor                        19/07/08        16:30

 Ser/Pl      N          00014-2                  000434
 19/07/08           CREA (C)        ALB2 (C)        CHOL (C)          TG (C)          TP2 (C)
 16:15:44           6.76            3.27              186             194             80.0
    admin                          >Test

               HCG-BETA (E-1)       TSH (E-2)
                  33,00             1,00
```

Figure B-158 Data Monitor report (monitor format)

Data Monitor/Report (report format)

```
                      ********************************************
                      *          HITACHI AUTOMATIC ANALYZER    *
                      ********************************************

ID                                  000434 DATE         18/09/08    17:05:23
S.NO.            N       00014-2           OPERATOR ID       admin
S.TYPE           Ser/Pl                    Name
AGE
SEX
DRAW DATE
DRAW TIME
PPEDILUTED       NO
TEST             RATIO   COI/MES    RESULT  UNIT        MODULE        EXPECTED VALUE    ALARM
TOTAL PROTEIN                         49.6  g/dL        C             ( -99999- 999999)
Chol                                   174  mg/dL       C             ( -99999- 999999)
Crea                                  1.18  mg/dL       C             ( -99999- 999999)
Na                                     125  mmol/L      C             ( -99999- 999999)
K                                      3.5  mmol/L      C             ( -99999- 999999)
Cl                                      87  mmol/L      C             ( -99999- 999999)
ALB                                     33  g/L         C             ( -99999- 999999)
```

Figure B-159 Data Monitor report (report format)

For more information, see *Data Monitor/Report* on page E-77.

Saving system parameters

Use the following procedure to make a backup of system parameters. This information can be restored by using the **Parameter Read** option in the **Parameter Read/Write** window, if required.

See *Restoring system parameters* on page B-312.

► To save system parameters on a storage medium

1 Wait until the system is in standby.

2 Insert a storage medium into the control unit computer.

- Floppy disk: New, blank floppy disk (3.5", 1.44 MB, formatted, PC compatible)
- DVD disk: A prepared DVD disk.
- USB storage devices: A tested and installed USB storage device

3 Choose **Utility** > **Maintenance**.

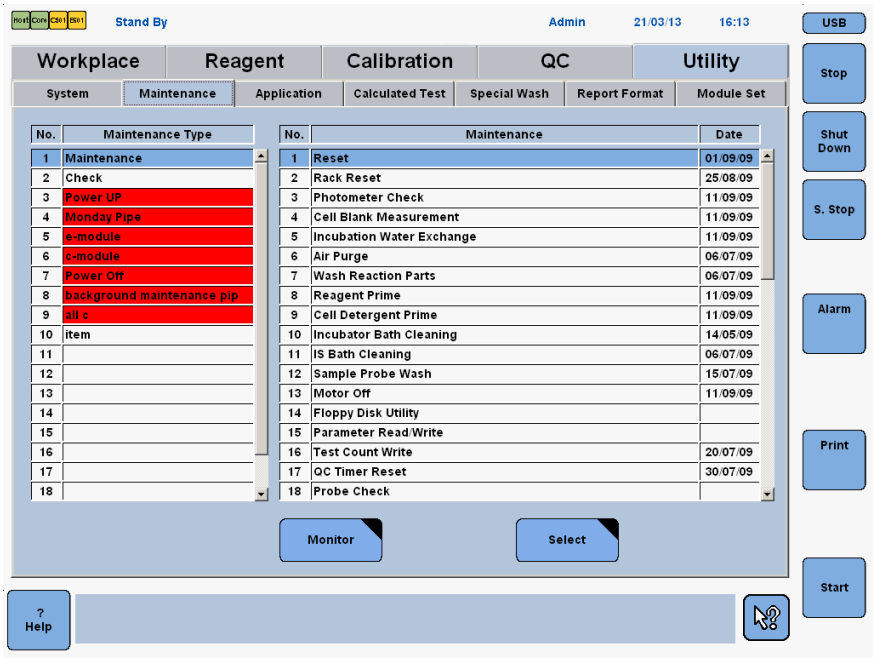


Figure B-160 Maintenance screen

4 Select **Maintenance** from the **Maintenance Type** list.

5 Select **(15) Parameter Read/Write** from the **Maintenance** Items list.

6 Choose **Select** to display the **Parameter Read/Write** window.

7 Select the required storage medium in the **Media** area.

Option	Description
Floppy Disk	Select this option to write the data to a floppy disk.
Mass Storage	Select this option to write the data to a mass storage. If a **USB** storage device is inserted, the instrument uses the USB as mass storage. If no USB storage device is inserted, the instrument uses a DVD disk as mass storage.

Table B-35 Media area

8 Select the **Parameter Write** option in the **Function** area and choose **Execute** to save parameters to storage medium after confirmation.

9 When processing is complete, eject the storage medium from the control unit computer and set aside for use later in this procedure.

For ejecting a USB storage device, see *Using a USB storage device* on page B-247.

The following system information is written:

Application settings [(a)]	Test registration number settings
Calculated and compensated test settings	Special wash settings
Report format settings	Module settings
System settings	Test assignment settings
Host communication settings	Rack assignment settings
Key settings	Host test code settings
Reagent level check settings	Profile settings
Maintenance pipe settings	Maintenance settings
ISE calibration settings	Power up pipe settings
Start condition settings	Review by exception settings
Scale settings for each graph	Test masking settings

Table B-36 System parameters stored by Parameter Read/Write function

(a) The units of an **e** 601 application are always the default ones. The units have to be manually edited after reading in the data from the disk.

10 Write the software version and the system configuration on the storage medium.

For more information about the software version, see:
Check Disk window on page E-466
(1) Check Disk on page C-43

■

Restoring system parameters

Use the following procedure to restore system parameters from a storage medium.

System configuration and software version

Do not restore system parameters on systems with a different configuration. e.g from a ce combination to a cce combination.

Do not restore system parameters on systems with a different software version.

► To restore system parameters to the system

1. Choose **Utility** > **Maintenance**.
2. Select 1 **Maintenance** from the **Maintenance Type** list on the left of the screen.
3. Select **(15) Parameter Read/Write** from the **Maintenance** Items list on the right.
4. Choose **Select** to open the **Parameter Read/Write** window.
5. Insert the storage medium into the control unit computer.
6. Select the required storage medium in the **Media** area.

Option	Description
Floppy Disk	Select this option to read the data from a floppy disk.
Mass Storage	Select this option to read the data from a mass storage. If a **USB** storage device is inserted, the instrument uses the USB as mass storage. If no USB storage device is inserted, the instrument uses a DVD disk as mass storage.

Table B-37 Media area

7. Select the **Parameter Read** option in the **Function** area.
8. Choose **Execute** and confirm with **Yes** to start loading the data.

■

Maintenance C

15 General maintenance C-3
16 Maintenance cu 150 C-47
17 Maintenance c 501 with ISE C-63
18 Maintenance e 601 C-115
19 Maintenance videos C-159

General maintenance

This chapter provides general information about maintenance for the **cobas** 6000 analyzer series. Concepts, such as maintenance pipes, maintenance types, parallel and background maintenance are described as well as instrument care. In addition, a combined maintenance schedule for all **cobas** 6000 modules is provided.

In this chapter *Chapter* 15

Overview C-5
General information on performing maintenance for the cobas 6000 analyzer C-6
Definitions C-8
Maintenance concept C-8
Maintenance pipes C-10
Defining and editing maintenance pipes C-11
Deleting maintenance pipes C-12
Performing maintenance items or pipes C-13
Using maintenance pipe functions C-15
Power Up Pipe function C-15
Start Up pipe function C-16
Sleep Pipe function with green wash rack C-17
Maintenance types C-18
Defining and editing maintenance types C-19
Tracking maintenance C-21
Maintenance report C-22
Maintenance schedules C-23
Daily maintenance C-24
Checks before start-up of the analyzer C-24
Maintenance items that can be performed in a Power Up pipe C-24
Maintenance items before shutdown C-25
Daily maintenance – only if last run has been interrupted C-25
Weekly maintenance C-26
Every two weeks maintenance C-27
Monthly maintenance C-28
Every three months maintenance C-29
Every six months maintenance C-29
As needed maintenance C-30

Automating instrument care with maintenance pipes C-32
Recommended maintenance pipes C-32
Power ON C-32
Sleep C-32
Weekly shutdown C-33
Extended power ON (1-2 days – only e 601) C-33
Extended power ON (2-7 days – only e 601) C-33
Extended power OFF (2-7 days – only e 601) C-33
Background and parallel maintenance C-34
Performing background maintenance C-36
Performing parallel maintenance C-37
Stopping background and parallel maintenance C-37
List of maintenance items C-38
List of maintenance checks C-43

Overview



Pay attention to the safety precautions!

Before performing maintenance for any part of the instrument, observe the general safety information.

See *General safety information* on page A-3.

The part Maintenance contains information about the following topics:

- General maintenance

 This chapter contains an overview of maintenance on the analyzer and describes how maintenance is managed.

- Module specific maintenance actions

 The module-specific maintenance actions are described in separate chapters.

 For more information, see:
 Maintenance cu 150 on page C-47
 Maintenance c 501 with ISE on page C-63
 Maintenance e 601 on page C-115

All of the software screens shown in this part are used as examples only. Your screens may vary depending on your system setup.

General information on performing maintenance for the cobas 6000 analyzer

For most maintenance actions, either a module has to be in standby or the analyzer has to be in shutdown status. This section explains what shutdown status is, how to put the analyzer in shutdown status, how to restart the analyzer, and how to release the analyzer in standby status after interlock function has generated an error message.

Make sure to put the analyzer in shutdown status or in an appropriate maintenance mode (for example, incubator bath cleaning mode) before replacing parts.

Keep the top cover of the analytical module closed for maintenance carried out with the system powered on. If a check or maintenance requires open covers, be careful not to touch any other than the aimed-at parts.

Operator time and System time

In the chapters of part C Maintenance the operator time and the system time for each maintenance item are mentioned.

The *operator time* is the estimated time that a trained person requires to perform this maintenance item.

The *system time* is the approximate time that the system requires to perform the required maintenance items. As most maintenance items can be performed in standby or shutdown status, the system time for shutdown of the analyzer (approximately 3 minutes) and for switching on the analyzer (approximately 12 minutes) is not included in the calculation of the system time.

See *List of maintenance items* on page C-38.

Shutdown status

Shutdown status is the condition where analytical module(s) and control unit are disconnected and the operation power switch is switched off. Power for keeping the reagents cool, however, is still supplied.

System time approximately 3 minutes

► To shutdown the analyzer

1. Choose **Shut Down** (global button) to display the **Shut Down** window.
2. Select the **Shut Down** option, choose **Execute** and confirm the shutdown.
3. Wait until the computer power supply turns off. Then, switch off the power switch of the printer and monitor.
4. Switch off the operation power switch on the left of the rack sampler unit.

■

If the power of the analyzer is switched off prior to the complete shutdown of the computer, the instrument may not start up properly when power is supplied again.

- Make sure the monitor indication has changed from shutdown to a state where nothing is displayed.
- Then, switch off the analyzer power switch.

System time approximately 12 minutes

► To switch on the analyzer

1 Switch on the analyzer's operation power switch located on the left of the rack sampler unit.

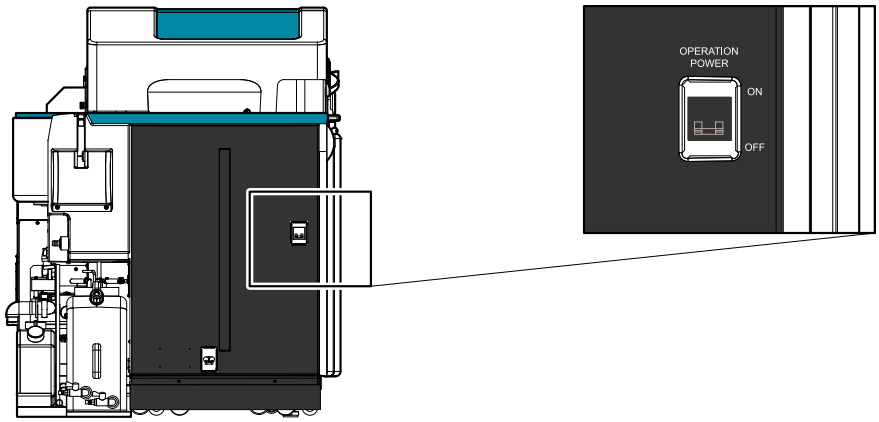


Figure C-1 Operation power switch

The system starts the initialization routine.

2 Switch on the computer of the control unit, the monitor, and the printer.

3 After initialization, the Logon screen displays. Enter your operator ID and password to log on.

4 Choose **OK** to gain access to the software and begin system operation.

■

If the logon mode is not activated (**Utility** > **System** (Page 3/4) > **Operator ID**), the software opens at the **System Overview** screen.

Definitions

Maintenance items — A single maintenance procedure

For a list of maintenance items, see *List of maintenance items* on page C-38.

System-controlled (automatic) maintenance — **Maintenance** items that are performed without operator interaction (such as (6) Air Purge)

Operator-controlled (interactive) maintenance — **Maintenance** items that require operator interaction (such as **(10) Incubator Bath Cleaning**).

User-definable (manual) maintenance — Users may define maintenance items specific for their laboratory (such as **Cleaning Sample Probe**). User-definable maintenance items are always maintenance actions that have to be performed manually.

Maintenance pipe — A combination of sequential maintenance items programmed into a fully automated procedure, which can be performed by the analyzer without operator intervention.

Maintenance pipe function — A function that automatically starts a maintenance pipe at a particular time (e.g., at power-up).

Maintenance type — A set of maintenance items (system-controlled, operator-controlled and user-definable) and maintenance pipes grouped according to certain functions (such as daily or weekly maintenance).

Maintenance concept

This section explains how the analyzer supports the operator when performing maintenance.

Performing maintenance items manually

Maintenance items can be performed manually on the **Utility** > **Maintenance** screen.

Operator-controlled and user-definable maintenance items cannot be part of a maintenance pipe. Thus, they have to be performed manually.

See *Performing maintenance items or pipes* on page C-13.

Maintenance pipes—performing maintenance items automatically

A maintenance pipe is a set of system-controlled maintenance items (batch set). You can use a maintenance pipe so that certain maintenance items occur in a certain sequence.

Before usage, maintenance pipes must be defined under **Utility** > **System** (**Page 2/4**) > **Pipe Setting**. They comprise up to ten maintenance items including parameters belonging to them.

Maintenance pipes can be executed in two different ways:

- Manually by the user
- Automatically by means of *maintenance pipe functions* at those events:
 - At power up of system (**Power Up Pipe** function)
 - Before start of analysis (**Start Up Pipe** function)
 - Before entering sleep mode (**Sleep Pipe** function)

For more information on maintenance pipes, see *Defining and editing maintenance pipes* on page C-11.

Maintenance types—scheduling and tracking maintenance items

Maintenance items and maintenance pipes can be assigned to a maintenance type according to certain functions (such as daily or weekly maintenance).

Within a maintenance type you can assign maintenance intervals (Period) and warning levels to each maintenance item and maintenance pipe. Thus, you can create and customize a maintenance schedule for any periodic maintenance tasks.

If a maintenance item or a maintenance pipe has been scheduled, you can track its status (date of last execution and warning level) on the **Maintenance** screen. The status of maintenance types is also displayed on the **System Overview** screen.

Maintenance types are configured in **Utility** > **System** (**Page 2/4**) > **Maintenance Setting**.

For more information on defining and using maintenance types, see:
Defining and editing maintenance types on page C-19
Tracking maintenance on page C-21

Maintenance report—recording maintenance

The analyzer records the execution of maintenance items in the **Maintenance Report**.

The **Maintenance Report** is requested through **Print** (global button) > **Utility** > **Maintenance Report**.

See *Maintenance report* on page C-22.

Parallel and background maintenance

Various maintenance procedures can be performed in parallel, meaning that one module can be performing a maintenance item while another module is performing a different maintenance item. Maintenance procedures may also be performed in background while the system is in the Operation mode.

See *Background and parallel maintenance* on page C-34.

Maintenance pipes

A maintenance pipe is a set of system-controlled maintenance items (batch set). Using maintenance pipes saves time by allowing the system to perform a series of maintenance items without operator intervention.

Be sure to note the relation between *maintenance pipes* and *maintenance pipe functions*:

Maintenance pipes

Before usage, maintenance pipes must be defined under **Utility** > **System** (**Page 2/4**) > **Pipe Setting**. The name of a pipe is freely definable, e.g. **Power Up pipe**.

Roche Diagnostics recommends using maintenance pipes for automating instrument care, but there are no pre-defined pipes on the system by default.

For more information, see:
Defining and editing maintenance pipes on page C-11
Recommended maintenance pipes on page C-32

Maintenance pipes can be executed manually by the user. Alternatively, they can be executed automatically by means of *maintenance pipe functions*.

Maintenance pipe functions

A maintenance pipe function triggers the system to start a maintenance pipe at one of those three particular times (events):

- At power-up or wake up (**Power Up Pipe** function)
- Before start of analysis (**Start Up Pipe** function)
- Before entering sleep mode after the last maintenance item is completed (**Sleep Pipe** function)

See *Maintenance pipe function* on page C-8.

Example

The **Power Up pipe** contains multiple maintenance items (Figure C-2). It can be executed manually or be assigned e.g., to the **Power Up Pipe** function. In the latter case, the pipe function will automatically start the maintenance pipe at power-up.

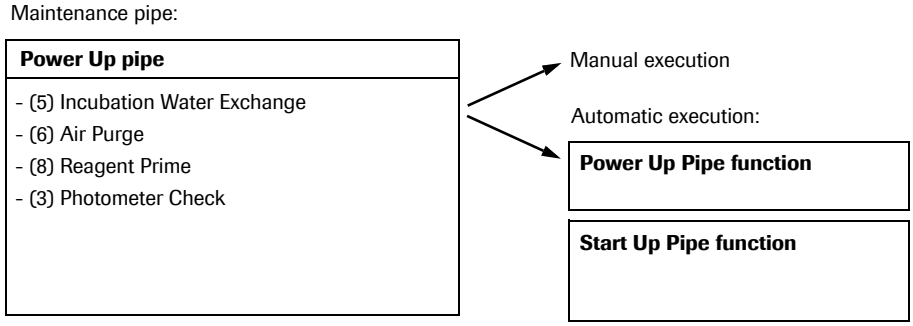


Figure C-2 Example of maintenance pipes and maintenance pipes functions

Note that:

- **Power On** is used as a name for a maintenance pipe. (This name is freely definable.)
- **Power Up Pipe** is a fixed name of a maintenance pipe function.

The following sections describe how maintenance pipes are defined, executed, and deleted.

Defining and editing maintenance pipes

Use the following procedure to program a series of maintenance items into a specific maintenance pipe. Up to ten items can be defined in each pipe. These items are performed one after the other. When a maintenance item is performed as part of a pipe, an asterisk appears on the left side of the date on the **Maintenance Report**.

See *Maintenance report* on page C-22.

► To edit a maintenance pipe or to define a new pipe

1 Choose **Utility** > **System** (**Page 2/4**) > **Pipe Setting** to display the **Maintenance Pipe Setting** window.

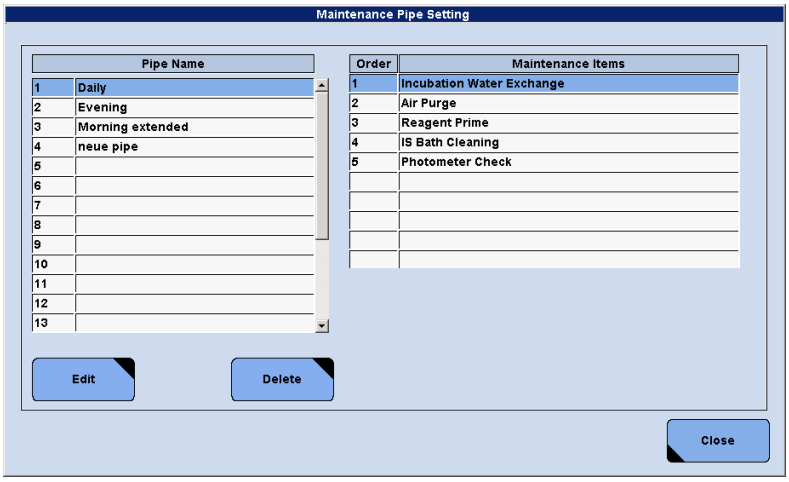


Figure C-3 Maintenance Pipe Setting window

2 Choose an existing pipe in the **Pipe Name** list to edit the pipe or choose the first blank line to define a new pipe. Choose **Edit** to display the **Edit Pipe** window.

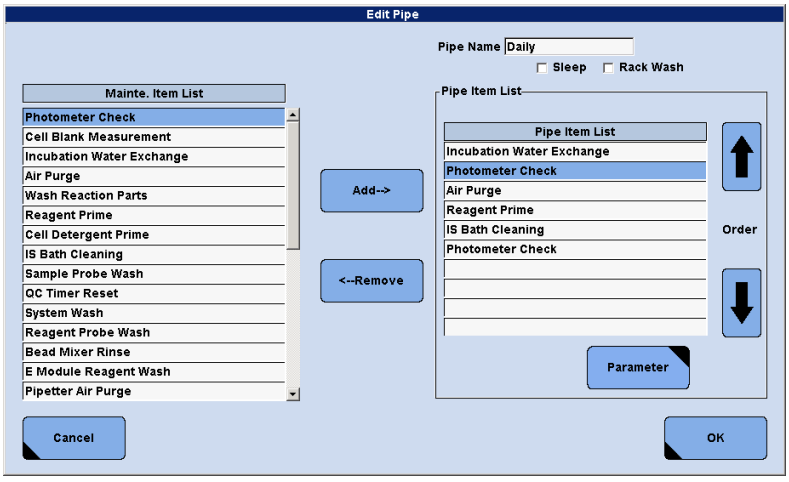


Figure C-4 Edit Pipe window

3 Type an unused name for the new pipe in the **Pipe Name** text box or edit the name of the existing pipe if you want to change its name.

To carry out washing with a green wash rack, select the **Rack Wash** check box. Set the green wash rack in the rack loader and execute the maintenance pipe. The maintenance pipe will be performed after the washing procedure.

The green wash rack procedure will not be performed if the pipe is executed as a **Power Up Pipe** or a **Start Up Pipe**.

4 Add a maintenance item to the **Pipe Item List** by choosing the maintenance item on the **Maintenance Item List**, then choose **Add**.

5 Choose **Parameter** to select or deselect specific modules or define the number of cycles performed depending on the maintenance item highlighted.

For more information about the parameters of the different maintenance items, see *Maintenance items* on page E-423.

6 Choose **OK** to save the settings and return to the **Edit Pipe** window.

7 Repeat steps 4 to 6 for all items that are to be included in the pipe.

8 Delete items from the pipe by choosing the appropriate item on the **Pipe Item List**, then choose **Remove**.

Items must be listed in the sequence that they are to be performed by the system. If the items are not in the desired order, choose the item to be reordered to highlight it, then choose the appropriate arrow to move the item up or down in the list.

9 Choose **OK** when the pipe settings are complete. The pipe then appears in the **Pipe Name** list in the **Maintenance Pipe Setting** window and as an option on **Utility** > **System** (**Page 2/4**) > **Power Up Pipe Setting**.

■

Deleting maintenance pipes

This section describes how to delete maintenance pipes.

► To delete a maintenance pipe

1 Choose **Utility** > **System** (**Page 2/4**) > **Pipe Setting**.

2 In the **Pipe Name** list, choose the name of the pipe to be deleted to highlight it.

3 Choose **Delete** and confirm with **Yes** to delete the maintenance pipe.

■

Performing maintenance items or pipes

Maintenance pipes are normally performed automatically by the system as a power up pipe or a start up pipe. But they can also be performed manually. Maintenance pipes can only be performed if they are part of a maintenance type.

To manually perform a maintenance pipe, it must be configured as an item of a maintenance type.

See *Defining and editing maintenance types* on page C-19.

If a single maintenance item is not part of a maintenance pipe, it can only be performed manually.

► To execute a maintenance item or pipe

1 If a maintenance pipe with the green wash rack option is to be executed, load the green wash rack on the system.

See:
Sleep Pipe function with green wash rack on page C-17
To prepare the wash rack on page C-70

2 Choose **Utility** > **Maintenance** to display the **Maintenance** screen.

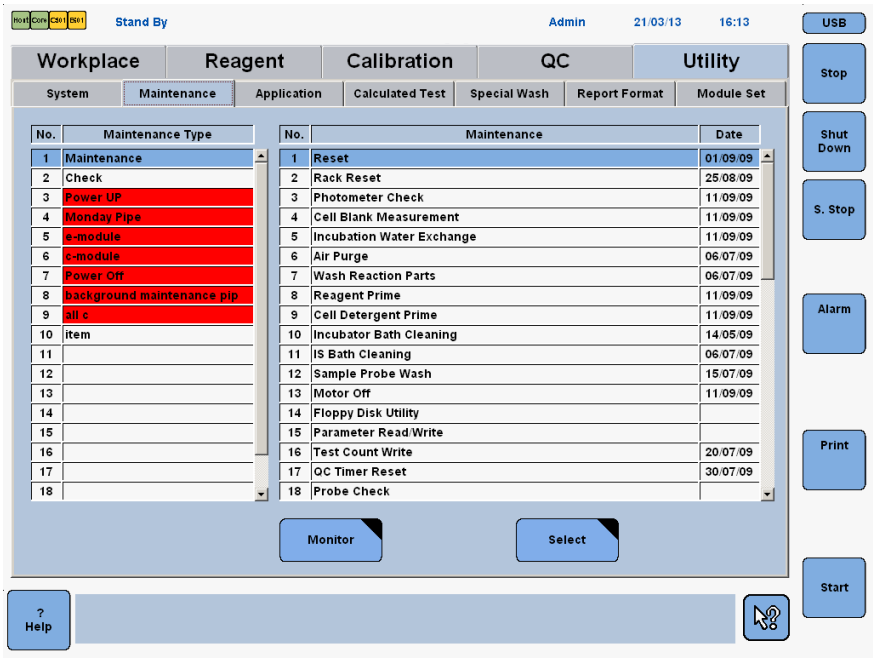


Figure C-5 Maintenance screen

3 Choose an entry from the **Maintenance Type** list.

- The entries **Maintenance** and **Check** are predefined. They include only maintenance items, but no pipes.
- A self-defined maintenance type can include both: Maintenance items and maintenance pipes.

4 Select the maintenance item or pipe to be performed from the **Maintenance** Item list.



A maintenance pipe can only be selected, if it was configured as an item of a maintenance type.

5 Choose **Select**.

6 Define any parameters required.

7 Choose **Execute**.

■

The maintenance pipe or item is performed. The date of the maintenance pipe or item is updated.

If the pipe is defined as a **Sleep** pipe, the system will enter in sleep mode after the pipe has been performed.

See *Sleep Pipe function with green wash rack* on page C-17.

Using maintenance pipe functions

Maintenance pipes can be performed automatically by the system by means of maintenance pipe functions. The system provides three maintenance pipe functions, which are described in the following.

Power Up Pipe function

Use the **Power Up Pipe** function to select a pipe to be performed at power up of the system. In addition, you can set a wake up time when the power up of the system—and thus the selected pipe—is performed. However, the wake-up time takes effect only if the system was put in sleep mode before (and not put to shutdown status).

No sleep function and green wash rack during Power Up Pipe

The sleep function and green wash rack procedure will not be performed during the **Power Up Pipe**, even though it is defined in the corresponding pipe settings.

► To activate the Power Up pipe function

1 Choose **Utility** > **System** (**Page 2/4**) > **Power Up Pipe Setting**.

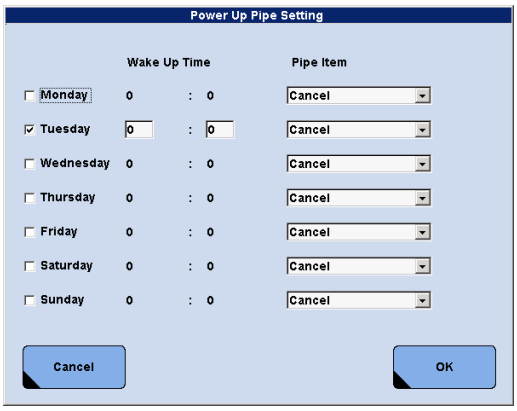


Figure C-6 Power Up Pipe window

2 Select the pipe to be performed at power up from the drop-down list box for each day of the week.

3 In case you want to set a wake-up time do the following:

- Select the check box to the left of the weekday for which you want to set a wake-up time.
- Set the time in the two boxes to the right of the check box.

4 Choose **OK**.

■

Start Up pipe function

The **Start Up Pipe** function is used to automatically perform a selected pipe before the start of analysis.

No sleep function and green wash rack during Start Up Pipe

The sleep function and green wash rack procedure will not be performed during the **Start Up Pipe**, even though it is defined in the corresponding pipe settings.

► To activate the Start Up pipe function

1 Choose **Start** (global button) or press the F2 key.

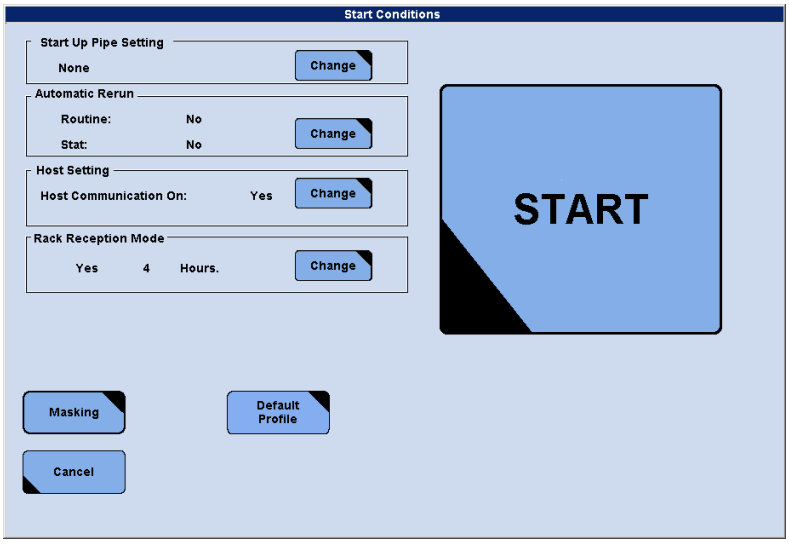


Figure C-7 Start Conditions screen

The **Start Up Pipe Setting** area displays the maintenance pipe currently selected as **Start Up** pipe. If no maintenance pipe is selected, None is displayed.

2 Choose **Change** in the **Start Up Pipe Setting** area.

3 Select the desired start up pipe from the list box on the **Pipe Function** window.

4 Choose **OK** to accept the change.

■

Once the start up pipe begins, the setting defaults to **None**.

Sleep Pipe function with green wash rack

The **Sleep Pipe** function enables the system to enter in sleep mode after a pipe has been performed. If the **Sleep Pipe** function is not activated (**Sleep** check box is not selected), the system turns to standby when a pipe is completed.

The sleep function and green wash rack procedure will not be performed if the pipe is executed as a **Power Up Pipe** or **Start Up Pipe**.

► To activate the Sleep Pipe function

1 Choose **Utility** > **System** (**Page 2/4**) > **Pipe Setting** to display the **Maintenance Pipe Setting** window.

2 Choose the pipe in the **Pipe Name** list to be performed as a sleep pipe.

3 Choose **Edit** to display the **Edit Pipe** window.

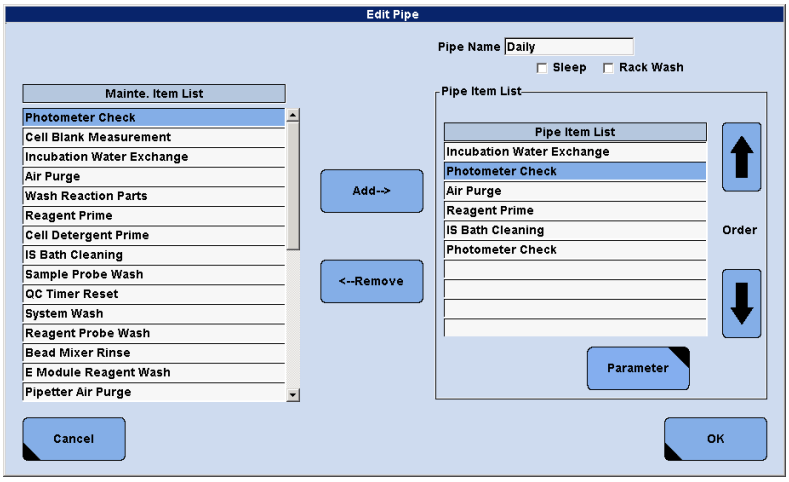


Figure C-8 Edit Pipe window

4 Select the **Sleep** check box to activate the **Sleep Pipe** function.

The system automatically turns to Sleep mode after the pipe is completed.

See *Performing maintenance items or pipes* on page C-13.

5 Select the **Rack Wash** check box in order to carry out washing with a green rack before pipe operation.

6 Choose **OK** to save the settings and return to the **Maintenance Pipe Setting** window.

■

Maintenance types

Maintenance items and maintenance pipes can be assigned to a maintenance type according to certain functions (such as daily, weekly, or monthly maintenance).

By means of maintenance types you can create a maintenance schedule. A maintenance interval can be assigned to each maintenance item and maintenance pipe within a maintenance type.

Two Maintenance types are predefined: **Maintenance** and **Check**.

Maintenance Contains all available maintenance items except check routines.

Check Contains all check routines.

Defining and editing maintenance types

Use the following procedure to assort a series of maintenance items into a specific maintenance type.

► To edit a maintenance type or define a new type

1 Choose **Utility** > **System** (**Page 2/4**) > **Maintenance Setting**.

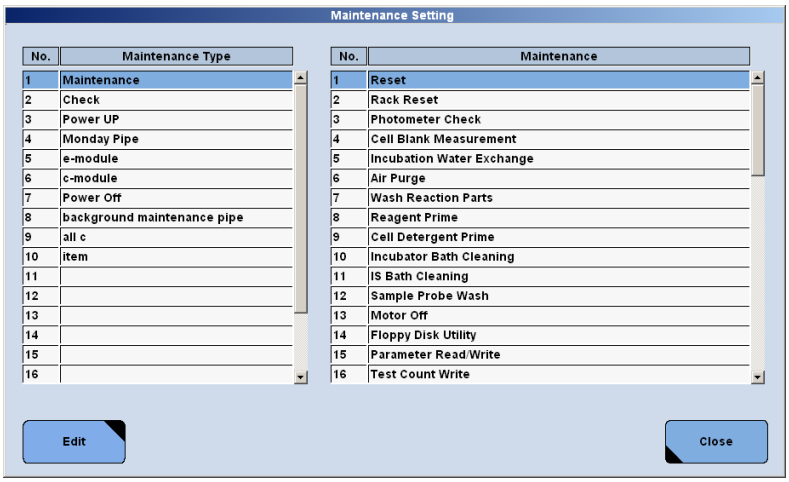


Figure C-9 Maintenance Setting window

2 If a new maintenance type is to be defined, select a free line from the **Maintenance Type** list, choose **Edit**, and proceed with step 3.

If an existing maintenance type is to be edited, select the appropriate line from the **Maintenance Type** list, choose **Edit**, and proceed with step 4.

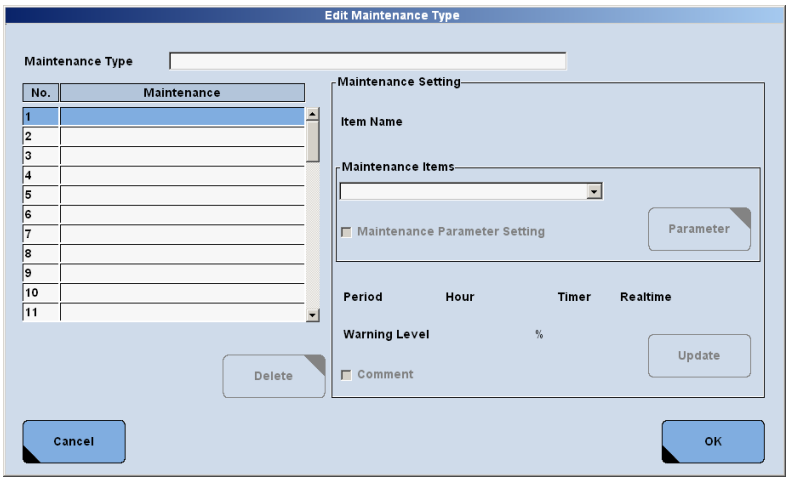


Figure C-10 Edit Maintenance Type window

3 Enter a name for the maintenance type in the text box at the top of the window.

4 Select an item from the **Maintenance Items** list box.

This list includes both maintenance items and user defined maintenance pipes.



The entry **User Definable** in this list can be used to define a new maintenance item that is not automated by the system (for example, clean instrument surfaces, check detergent level, etc.).

5 Choose **Parameter** to display the maintenance parameter window for the selected maintenance item, if available. Use this window to define parameters for the selected maintenance item.

For more information about the different **Maintenance Parameter** windows, see *Maintenance items* on page E-423.

6 For maintenance tracking, enter the frequency in the text box and select the time period (**Hour**, **Day** and **Month**) from the **Period** list box.

7 Select a timer function from the **Timer** list box:

- **Realtime**: The actual time
- **Power On**: Cumulative power-on time of the analyzer (excluding sleep time)
- **Operation**: Cumulative operation time

Power on time and operation time are both listed on the **Maintenance Report** (**Print** > **Utility** > **Maintenance Report**).

If a frequency period is not required, enter **0** in the field to cancel.

See *Maintenance report* on page C-22.

8 Enter the warning level (%) in the **Warning Level** text box.

Example: If you define a period of 10 hours in real time and a warning level of 90%, the analyzer will remind you to perform the maintenance item after 9 hours.

9 Select the **Comment** check box to display the **Comment** field on the appropriate maintenance item window and to print the comment on the **Maintenance Report**.

10 Choose **Update** to add the item to the **Maintenance Items** list.

11 Repeat steps 3 to 10 for all maintenance items for the maintenance type.

12 Choose **OK** to save the collection and its settings and close the **Edit Maintenance Type** window.

■

Tracking maintenance

If you have assigned a maintenance interval to a maintenance item or a maintenance pipe within a maintenance type, the analyzer reminds you when a maintenance item or pipe has to be performed.

Maintenance tracking is done on the **Maintenance** screen. The status of maintenance actions is also displayed on the **System Overview** screen.

► To display the maintenance status

1 Choose **Utility** > **Maintenance** to display the **Maintenance screen**.

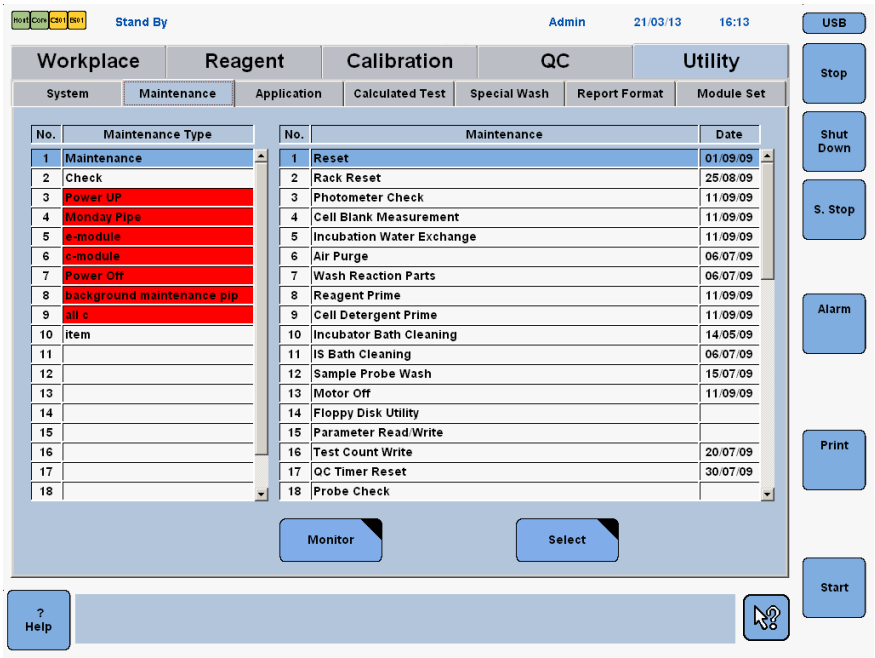


Figure C-11 Maintenance screen

The following information is displayed:

- The maintenance type is highlighted in yellow or red if any item or pipe for this maintenance type exceeds its warning level or its maintenance interval.
- The date the maintenance item or pipe was last performed.
- The date in the item list is highlighted in yellow if the maintenance item or pipe exceeds its warning level.
- The date in the item list is highlighted in red if the maintenance item or pipe exceeds its maintenance interval.

2 If you need more information about the maintenance status of a particular maintenance type, select a maintenance type and then a maintenance item or pipe from the **Maintenance** Item list.

3 Choose **Monitor** to view the status of the selected maintenance item or pipe.

For more information about the **Maintenance Monitor** window, see *Maintenance Monitor window* on page E-422.

■

Maintenance report

The analyzer records the execution of maintenance items in the **Maintenance Report**.

The **Maintenance Report** is requested through **Print** (global button) > **Utility** > **Maintenance Report**.

```
                                          Maintenance Report       02/02/06       14:27

POWER ON TIME                                984               HOURS
OPERATION                                     24               HOURS

MAINTENANCE TYPE:          Maintenance                                          Page         1
MODULE:                    E
MAINTENANCE
      DATE       TIME      OP.ID           COMMENTS
Cell Wash
Reagent Line Purge
Wash Reaction Parts
Reagent Flowpath Wash
System Wash
        02/01/10 13:45     admin
        01/12/17 12:14     admin
Photometer Check
Cell Blank Measurement
Incubation Water Exchange
Air Purge
Reset
        02/01/31 11:36     admin
        02/01/25 09:56     admin
        02/01/25 09:54     admin
        02/01/25 09:52     admin
        02/01/24 15:08     admin
        02/01/22 11:03     admin
        02/01/10 15:03     admin
        02/01/08 10:09     admin
        01/12/19 14:45     admin
```

Figure C-12 Maintenance report

For more information about the **Maintenance Report**, see *Maintenance Report* on page E-167.

Maintenance schedules

The following section provides you with an overview of the maintenance actions required for proper instrument care. The information is sorted according to the frequency in which the actions must be performed and includes the module and type of actions required.

Incorrect results after longtime power off

If the instrument has been powered off for a week or more, accuracy may deteriorate.

- Check the instrument performance before starting up operation again.
- For performance check details, consult your Roche service representative.

Spare parts

For proper instrument care use only original spare parts provided by Roche Diagnostics.

- The necessary spare parts are listed in the description of the corresponding maintenance action.
- For ordering the spare parts, please contact your Roche service representative.

Daily maintenance

The following tables provide you with an overview of the maintenance actions that must be performed on a daily basis.

Checks before start-up of the analyzer

There are various conditions that need to be checked before a system start-up. Therefore it is important to inspect the system prior to switching on the analyzer.

For more information, see *Starting inspection* on page B-30.

Maintenance items that can be performed in a Power Up pipe

Laid out below is a list of maintenance items that are suitable to be used in connection with the **Power Up Pipe** function or the **Start Up Pipe** function.

For more information, see:
Maintenance pipes on page C-10
Power Up Pipe function on page C-15
Start Up pipe function on page C-16

Visual checks at start-up

Note that even though a maintenance pipe can be executed automatically some maintenance items require visual checks by the operator.

Item	Action type: Power Up pipe with visual checks	Module
(5) Incubation Water Exchange	Check the temperature of the incubator bath on the System Overview screen before starting analysis.	**c** 501
(6) Air Purge	Check the syringes and the tubing system against leakage and air bubbles.	**c** 501
(8) Reagent Prime	ISE: All	**c** 501 (ISE)
(11) IS Bath Cleaning	Check against solid residual at the upper part of the IS baths.	**c** 501 (ISE)
Smart. Com Essential information upload	Backup function; configuration settings and patient data are uploaded from the flash memory of the analyzer to the **cobas** link PC.	**c** 501**e** 601
(3) Photometer Check	Check the photometer values on the **Print View** window.	**c** 501

Table C-1 Instrument care - daily (Power On)

Maintenance items before shutdown

Item	Action type: Cleaning	Module	See
Processing green wash rack	Position 1: Sample Cleaner 1 (cycles: 5) Position 2: SysClean (cycles: 15) Position 3: Activator (cycles: 15) The cycles are set in the **Wash Rack Sampling** area of the **Utility** > **System** screen: • **Photometric** refers to Position 1 • **ISE** refers to Position 2 and 3. Can be included in a sleep pipe.	**c** 501	C-69
Cleaning sample probe, reagent probes, ISE probe and ISE sipper nozzle	Clean the probes, shield pipe and the ISE sipper with alcohol (e.g. isopropyl alcohol or ethanol). Upon detection of abnormal sample aspiration caused by a clot, the sample probe is washed automatically by the analyzer.	**c** 501	C-73
Cleaning the drain port for high concentrated waste	Apply deionized water to the waste solution nipple at the rear of the **c** 501 to rinse off crystals.	**c** 501 (ISE)	C-76
Emptying and cleaning the concentrated waste tank	Empty the concentrated waste tank at the rear of the analyzer. Wear protective gloves when performing this procedure. Contents of the waste solution reservoir are potentially biohazardous.	**cu** 150	C-50
Cleaning cell rinse nozzles	Clean the cell rinse nozzles with deionized water.	**c** 501	C-75

Table C-2 **cu** 150 module-specific and **c** 501 module-specific instrument care - daily before shutdown

Item	Action type: Cleaning	Module	See
Cleaning probes and sippers: Sample probe	Wipe the outer surfaces of the probe and probe tip with a gauze pad soaked in deionized water. If the probe still appears dirty, wipe the outer surfaces with a gauze pad soaked in alcohol (e.g. isopropyl alcohol or ethanol). Then with deionized water again.	**e** 601	C-118
Cleaning probes and sippers: Reagent probe	Wipe the outer surfaces of the probe with a gauze pad soaked in alcohol. Then with deionized water again.	**e** 601	C-118
Cleaning probes and sippers: Sipper probes for measuring cells 1 and 2	Wipe the outer surfaces of the probe with a gauze pad soaked in alcohol. Then with deionized water again.	**e** 601	C-118
Cleaning probes and sippers: Pre-wash sipper and dispenser probe	Wipe the outer surfaces of the probe with a gauze pad soaked in alcohol. Then with deionized water again.	**e** 601	C-118

Table C-3 **e** 601 module-specific instrument care - daily before shutdown

Daily maintenance – only if last run has been interrupted

Item	Action	Module	See
Finalization	The system is primed with water and the measuring cells are filled with ProCell. Finalization must be performed if analyzer did not complete Post Operation at the end of the day, for example, due to a system stop.	**e** 601	C-151

Table C-4 Instrument care **e** 601 module - daily if last run interrupted

Weekly maintenance

The following tables provide you with an overview of the maintenance actions that must be performed on a weekly basis.

Item	Action	Module	See
Cleaning the reaction system (7) Wash Reaction Parts	Perform maintenance item **(7) Wash Reaction Parts** to clean sample probe with Sample Cleaner 1 (1.8 mL) and reagent probes and reagent cells with reagent from NaOH-D cassette (application code 947).	**c** 501	C-77
(4) Cell Blank Measurement	Perform maintenance item **(4) Cell Blank Measurement** to obtain new photometric reference.	**c** 501	C-78
Cleaning the rinse stations Sample probe Reagent probes ISE probe	Clean rinse stations using cotton swabs moistened with 2% EcoTergent solution. Inject 2% EcoTergent solution and deionized water. Clean the drying cylinder of the sample probe rinse station with cotton swabs moistened with alcohol (e.g. isopropyl alcohol or ethanol).	**c** 501	C-81
Removing and manually cleaning the IS bath	Put the analyzer in shutdown status or the module in standby and remove the IS bath. Wash away any crystals or contamination in the IS bath with deionized water.	**c** 501 (ISE)	C-83
Cleaning the cell covers (metal plates)	Wipe front and rear faces of cell covers using a gauze pad moistened with alcohol. Wipe openings of cell covers using a cotton swab.	**c** 501	C-79

Table C-5 **c** 501 module-specific instrument care - weekly

Item	Action	Module	See
Cleaning ProCell/CleanCell nozzles and replace reservoirs	Wipe the ProCell/CleanCell reservoir filling nozzle and electrodes with a cotton swab soaked in deionized water. Lift the sipper supply unit and exchange the reservoirs. Clean the inside of reservoir positions by wiping them with a cotton swab soaked in deionized water. Place new reservoirs in the reservoir positions and push the sipper nozzle unit back into place.	**e** 601	C-121
Cleaning mixing station and separation stations of the Pre-wash area Cleaning incubator Cleaning vortex mixing station	Wipe the surfaces of all components with a gauze pad soaked in deionized water. Afterwards, dry it with gauze pads and cotton swabs. Ensure that the Pre Wash Mixer, Pre Wash separation stations and their holes are not clogged. Check also that incubator holes are not clogged.	**e** 601	C-125 C-128 C-130
Cleaning microbead mixer	Very carefully wipe the microbead mixer paddle with a lint-free gauze square soaked in alcohol (e.g. isopropyl alcohol or ethanol) from top to bottom. Then use a brush to clean the 4 propeller plates with alcohol. Repeat the procedure using deionized water instead of alcohol.	**e** 601	C-132
Cleaning rinse stations Sipper station Mixer station Reagent station	Clean the inside of each rinsing station using a cotton tipped applicator stick soaked in alcohol, followed by a cotton tipped applicator stick soaked in deionized water. Fill a 50 mL syringe (with tubing attached) with EcoTergent. Inject the cleaning solution (empty the syringe) into the drain hole of the rinse bath. Fill a 50 mL syringe with deionized water. Inject the deionized water (empty the syringe) into the drain hole of the rinse bath.	**e** 601	C-134

Table C-6 **e** 601 module-specific instrument care - weekly

Every two weeks maintenance

The following table provides you with an overview of the maintenance actions that must be performed at least once every two weeks.

Item	Action	Module	See
Liquid flow path cleaning	Fill SysClean cups with SysClean to the lower limits (approx. 9 mL/cup) and perform maintenance item **(27) Liquid Flow Cleaning**. System time: approx. 30 min. This function will clean the sipper probe, tubings, and measuring cells. Perform liquid flow path cleaning at least every two weeks or after 2500 to 3000 determinations per channel, whichever comes first.	**e** 601	C-137

Table C-7 Instrument care - every two weeks

Monthly maintenance

The following table provides you with an overview of the maintenance actions that must be performed on a monthly basis.

Item	Action	Module	See
Cleaning the water tank	• Shut down the analyzer and disconnect the water tank. • Wipe float assembly with gauze pads. Rinse tank thoroughly with deionized water. If water tank is considerably contaminated, clean with 0.5% sodium hypochlorite solution using a brush. Rinse tank thoroughly with deionized water.	**cu** 150	C-53
Replacing reaction cells	Put the module in shutdown or motor off status. • Remove reaction cells. • Clean incubator bath and its drain filter (see below). • Install new reaction cells. • Perform maintenance item **(7) Wash Reaction Parts** then perform maintenance item **(4) Cell Blank Measurement**.	**c** 501	C-86
Cleaning the incubator bath	Put the module in shutdown status or in Incubator bath cleaning status. In case the analyzer is already in shutdown status, drain incubator bath water. Otherwise, perform maintenance item **(10) Incubator Bath Cleaning**. • Detach cell rinse unit and reaction cells. Clean incubator bath and photometer windows using lint-free gauze pads. Clean and rinse the filter with deionized water. • Reattach reaction cells and cell rinse unit. • Refill the bath with ~ 500 mL deionized water and start up the analyzer performing maintenance item **(5) Incubation Water Exchange** or—if **(10) Incubator Bath Cleaning** is used—choose **Continue** to release the incubator bath cleaning mode. Perform maintenance items **(7) Wash Reaction Parts** and **(4) Cell Blank Measurement** (see above).	**c** 501	C-88
Cleaning the detergent aspiration filters	Clean aspiration filters, which are attached to the tube ends, each time you replace a reagent bottle or at least once a month. • Remove the filter from the tube end. • Clean and rinse the filter with deionized water. • Perform maintenance item **(9) Cell Detergent Prime**.	**c** 501	C-94
Cleaning the ISE Ref. (KCl) aspiration filter	Clean aspiration filter each time you replace the ISE Ref. bottle or at least once a month. • Remove the filter from the tube end. • Clean and rinse the filter with deionized water. • Perform maintenance item **(8) Reagent Prime** with the **Ref** option selected.	**c** 501 (ISE)	C-84
Cleaning the filters behind the front doors	Remove dust from filter with a vacuum cleaner	**c** 501	C-96
Cleaning the filter of the rack sampler unit	Remove dust from filter with a vacuum cleaner	**cu** 150	C-57

Table C-8 Instrument care - monthly

Every three months maintenance

The following table provides you with an overview of the maintenance actions that must be performed at least once every three months.

Item	Action	Module	See
Cleaning the ultrasonic mixers	Include this maintenance in the monthly cleaning of the incubator bath. If the ultrasonic mixers were used for more than three months, or after 225.000 tests, whatever comes first. • Wipe surface of ultrasonic mixers with cotton swabs moistened with 2% EcoTergent solution. • Wipe off the detergent with cotton swabs moistened with deionized water. • At the end of the maintenance, perform maintenance check **(7) Cuvette Mixing**.	**c** 501	C-98
Replacing e 601 pinch valve tubing	• Perform maintenance item **(26) MC Exchange** before removing the tubes, to avoid dripping off fluid on the valves. • Shut down the system or put the **e** 601 module into standby mode. • Remove all 4 pinch valve tubings from the fittings. • Use a dry gauze pad to absorb liquid which drains from the acrylic block or from the tubing. • Take new pinch valve tubing and insert it through the pinch valve. • Slide the ends of the tubing over each fitting. • Perform maintenance item **(24) Sipper Air Purge** and **(25) MC Preparation** before resuming operation.	**e** 601	C-140

Table C-9 Instrument care - every three months

Every six months maintenance

The following table provides you with an overview of the maintenance actions that must be performed at least every six months.

Item	Action	Module	See
Cleaning the inlet water filter	• Put the analyzer in shutdown status. • Place a 500 mL beaker beneath the inlet water manifold. • Disconnect the inlet water hose. • Clean the filter thoroughly with deionized water, then reinstall the filter.	**cu** 150	C-58
Cleaning the cooling fans	• Put the analyzer in shutdown status. • Remove dust from filter with a vacuum cleaner or use a brush.	**cu** 150	C-60
Replacing the photometer lamp	Replace the photometer lamp if the lamp has been used for more than six months, for more than 750 hours of continuous powered-on time or if the photometer check value exceeds 14000, whatever comes first. • If any of the current photometer check data exceeds 14000, check light path for contamination or scratches. Check that cell no. 1 is at least half filled with water. • Replace the photometer lamp if necessary. • Wait 30 min for the photometer lamp to stabilize, then, perform maintenance item **(4) Cell Blank Measurement** (necessary to compensate for a change in light intensity).	**c** 501	C-101

Table C-10 Instrument care - every six months

As needed maintenance

The following table provides you with an overview of the maintenance actions that must be performed as needed.

Item	Cause	Action	Module	See
Emptying the concentrated waste tank	In spite of emptying the tank at the beginning of the day, it can get full in the course of a working session. An alarm is issued when the concentrated waste tank gets full.	• Empty the concentrated waste tank at the rear of the analyzer. • Wear protective gloves when performing this procedure. Contents of the waste tank are potentially biohazardous.	**cu** 150	
Cleaning the detergent aspiration filters	When replacing cell detergents (Cell Wash Solution I / NaOH-D, Cell wash Solution II / Acid Wash) behind the front doors. An alarm is issued on the **System Overview** screen when a detergent bottle gets empty (**Reagent Preparing** > **Reagent Load List** in the **Work Flow Guide**)	• Remove the filter from the tube end. • Clean and rinse the filter with deionized water. • Perform maintenance item **(9) Cell Detergent Prime**.	**c** 501	C-106
Cleaning the ISE Ref. (KCl) aspiration filter	When replacing ISE Ref. bottle. An alarm is issued on the **System Overview** screen when the ISE Ref. bottle is empty (**Reagent Preparing** > **Reagent Load List** in the **Work Flow Guide**)	• Remove the filter from the tube end. • Clean and rinse the filter with deionized water. • Perform maintenance item (8) Reagent Prime with the Ref option selected.	**c** 501 (ISE)	C-106
Cleaning the ultrasonic mixers	If the ultrasonic mixers were used for more than three months, or after 225.000 tests, whatever comes first.	• Wipe surface of ultrasonic mixers with cotton swabs moistened with 2% EcoTergent solution. • Wipe off the detergent with cotton swabs moistened with deionized water. • At the end of the maintenance, perform maintenance check **(7) Cuvette Mixing**.	**c** 501	C-108
Replacing the photometer lamp	If the photometer lamp has been used for more than six months, for more than 750 hours of continuous powered-on time or if the photometer check value exceeds 14000, whatever comes first.	• If any of the current photometer check data exceeds 14000, check light path for contamination or scratches. Check that cell no. 1 is at least half filled with water. • Replace the photometer lamp if necessary. • Wait 30 min for the photometer lamp to stabilize, then, perform maintenance item **(4) Cell Blank Measurement** (necessary to compensate for a change in light intensity).	**c** 501	C-108

Table C-11 **cu** 150 module-specific and **c** 501 module-specific instrument care - as needed

Item	Cause	Action	Module	See
Replacing nozzle tips on cell rinse nozzles	If the nozzle tips are worn but latest after 225.000 tests.	• Put the analyzer in Maintenance mode or Shutdown status. • Remove the cell rinse unit. • Replace nozzle tip. • Attach the cell rinse unit. • Check the alignment of the new nozzle tip. • Perform a **(3) Mechanism Check** (10 cycles).	**c** 501	C-106
Draining the vacuum tank	Alarm (Liquid in Vacuum Tank) is issued.	• Remove the cap holding the drain tube of the vacuum tank. • Drain the waste solution into a beaker.	**c** 501	C-109
Cleaning instrument surfaces	Spills on the instrument surface could be potentially biohazardous and damage the material.	• Clean up spills immediately using a paper towel moistened with disinfectant.	**cu** 150 **c** 501	C-61 C-110

Table C-11 **cu** 150 module-specific and **c** 501 module-specific instrument care - as needed

Item	Action	Module	See
Cleaning ProCell/CleanCell stand and aspiration tubes	If crystallization is observed, wipe the aspiration tubes and stand for the ProCell/CleanCell bottles with a lint-free gauze pad soaked in deionized water. Then dry them with dry gauze pads.	**e** 601	C-143
Cleaning reagent disk and compartment	If the disk appears dirty, use a lint-free gauze pad soaked with alcohol (e.g. isopropyl alcohol or ethanol). Then use gauze pads soaked with deionized water. Afterwards, dry with cloth or lint-free towels.	**e** 601	C-146
Cleaning solid waste compartment	Pull out the draw unit. Remove both waste liners. Wipe the containers (inside and outside) with gauze pads soaked in disinfectant. Then wipe with gauze pads soaked with deionized water. Place a new Waste Liner M into each waste container and updated it.	**e** 601	C-148
Finalization	The system is primed with water and the measuring cells are filled with ProCell. Finalization must be performed if analyzer did not complete Post Operation at the end of the day, for example, due to a system stop.	**e** 601	C-151
Cleaning instrument surfaces	Spills on the instrument surface could be potentially biohazardous and damage the analyzer. Clean up spills immediately using a paper towel moistened with disinfectant.	**e** 601	C-150

Table C-12 **e** 601 module-specific instrument care - as needed

Automating instrument care with maintenance pipes

A maintenance pipe is a set of system-controlled maintenance items.

Maintenance pipes can be executed manually by the user. Alternatively, they can be executed automatically by means of maintenance pipe functions.

Moreover, maintenance pipes can be programmed to automatically put the analyzer in sleep mode after the last maintenance item is completed (**Sleep Pipe** function).

Maintenance pipes are configured under **Utility** > **System** (**Page 2/4**) > **Pipe Setting**.

For more information on defining and using maintenance pipes, see:
Defining and editing maintenance pipes on page C-11
Power Up Pipe function on page C-15
Start Up pipe function on page C-16
Sleep Pipe function with green wash rack on page C-17
List of maintenance items on page C-38

Recommended maintenance pipes

This section shows the maintenance pipes that Roche Diagnostics recommends for proper use of the analyzer. The maintenance items must be programmed in the order listed here for the pipe to be performed correctly.

For more information on defining and using maintenance pipes, see *Defining and editing maintenance pipes* on page C-11.

Power ON

Maintenance Item	Module
(5) Incubation Water Exchange	**c** 501
(6) Air Purge	**c** 501
(8) Reagent Prime (ISE)	**c** 501
(11) IS Bath Cleaning	**c** 501
Smart. Com Essential information upload	**c** 501, **e** 601
(3) Photometer Check	**c** 501

Table C-13 Maintenance pipe Power ON

For more information on, see:
Power Up Pipe function on page C-15
Start Up pipe function on page C-16

Sleep

Maintenance Item	Module
Processing green wash rack	**c** 501

Table C-14 Maintenance pipe Sleep

For more information, see *Sleep Pipe function with green wash rack* on page C-17.

Weekly shutdown

Maintenance Item	Module
(7) Wash Reaction Parts	**c** 501
(4) Cell Blank Measurement	**c** 501

Table C-15 Maintenance pipe Weekly shutdown

Extended power ON (1-2 days – only e 601)

Execute this maintenance pipe when the system is idle for one to two days, for example, after weekends. After more than one day the **e** 601 measuring cell needs to be conditioned; therefore, maintenance item **(25) MC Preparation** is integrated in this maintenance pipe.

Maintenance Item	Cycles
(37) System Air Purge (E Module)	10
(8) Reagent Prime (Pre-wash Probe)	5
(25) MC Preparation	5

Table C-16 Maintenance pipe Extended power ON (1-2 days)

Extended power ON (2-7 days – only e 601)

Execute this maintenance pipe when the system is idle for two to seven days. In comparison to the maintenance pipe Extended power ON (1-2 days – only e 601) this recommendation includes priming the e module reagent lines.

Maintenance Item	Cycles
(24) Sipper Air Purge	5
(23) Pipetter Air Purge	10
(8) Reagent Prime (Pre-wash Probe)	5
(8) Reagent Prime (Reagent)	2
(25) MC Preparation	30

Table C-17 Maintenance pipe Extended power ON (2-7 days)

Extended power OFF (2-7 days – only e 601)

Execute this maintenance pipe before shutting down the system for two to seven days.

Maintenance Item	Cycles
(8) Reagent Prime (Pre-wash Probe)	5
(8) Reagent Prime (Reagent)	5
(33) Empty PC/CC Reservoir	–
(31) Pre-wash Sipper Air Purge	10

Table C-18 Maintenance pipe Extended power OFF (2-7 days)

Background and parallel maintenance

Background Maintenance

Background maintenance is used to perform maintenance functions on one or more modules while the system is still in Operation mode. In Background maintenance one or more modules are masked.

Parallel Maintenance

You may use parallel maintenance to perform different maintenance items on different modules while the system is in the standby mode.

Pipe functions can also be performed as background maintenance. Background maintenance can be stopped using **Cancel Maintenance** on the **System Overview** screen. However, not all maintenance items can be stopped once started.

For more information, see:
Performing background maintenance on page C-36
Performing parallel maintenance on page C-37

The following tables display the maintenance items and checks and indicate in which operation mode they can be performed.

✓	This item can be performed

Maintenance Item	c 501			e 601		
	Standby	Background	Parallel	Standby	Background	Parallel
(1) Reset	✓	✓	✓	✓	✓	✓
(2) Rack Reset	✓			✓		
(3) Photometer Check	✓	✓	✓			
(4) Cell Blank Measurement	✓	✓	✓			
(5) Incubation Water Exchange	✓	✓	✓			
(6) Air Purge	✓	✓	✓			
(7) Wash Reaction Parts	✓	✓	✓			
(8) Reagent Prime	✓	✓	✓	✓	✓	✓
(9) Cell Detergent Prime	✓	✓	✓			
(10) Incubator Bath Cleaning	✓	✓	✓			
(11) IS Bath Cleaning	✓	✓	✓			
(12) Sample Probe Wash	✓	✓	✓			
(19) System Wash				✓	✓	✓
(20) Reagent Probe Wash				✓	✓	✓
(21) Bead Mixer Rinse				✓	✓	✓
(22) E Module Reagent Wash				✓	✓	✓
(23) Pipetter Air Purge				✓	✓	✓
(24) Sipper Air Purge				✓	✓	✓
(25) MC Preparation				✓	✓	✓
(26) MC Exchange				✓	✓	✓
(27) Liquid Flow Cleaning				✓	✓	✓
(28) Inventory Update				✓	✓	✓
(29) Manual Cleaning				✓	✓	✓
(30) Pre-wash Sipper Rinse				✓	✓	✓

Table C-19 Available operation modes for Maintenance items (Sheet 1 of 2)

Maintenance Item	c 501			e 601		
	Standby	Background	Parallel	Standby	Background	Parallel
(31) Pre-wash Sipper Air Purge				✓	✓	✓
(32) Finalization				✓	✓	✓
(33) Empty PC/CC Reservoir				✓	✓	✓
(34) Initial Bead Mixing				✓	✓	✓
(35) Reagent Capping				✓	✓	✓
(36) AssayCup Discarding				✓	✓	✓
(37) System Air Purge (E Module)				✓	✓	✓
(38) System Prime (E Module)				✓	✓	✓
(39) Change Light Source Lamp	✓	✓	✓			

Table C-19 Available operation modes for Maintenance items (Sheet 2 of 2)

Maintenance Check	c 501			e 601		
	Standby	Background	Parallel	Standby	Background	Parallel
(2) ISE Check	✓	✓	✓			
(3) Mechanism Check	✓	✓	✓	✓	✓	✓
(4) Sample Barcode Reader Check	✓			✓		
(5) Reagent Barcode Reader Check	✓	✓	✓	✓	✓	✓
(6) Cassette Loading Check	✓	✓	✓			
(7) Cuvette Mixing	✓	✓	✓			
(8) Reagent Short Sensor Check				✓	✓	✓
(9) Sample Pipetting Check				✓	✓	✓
(10) Reagent Pipetting Check				✓	✓	✓
(11) Cap Opener Check				✓	✓	✓
(12) Bead Mixer Check				✓	✓	✓
(13) Gripper Check				✓	✓	✓
(14) Magazine Exchange Check				✓	✓	✓
(15) Sipper Check				✓	✓	✓
(16) Pre-wash Probe Check				✓	✓	✓
(17) Pre-wash Gripper Check				✓	✓	✓

Table C-20 Available operation modes for Maintenance checks

Performing background maintenance

Use the following procedure to perform maintenance on one analytical module while the system is in operation.

When performing maintenance actions on a masked module, ensure that nobody unmasks and starts the module.

► To perform background maintenance

1 Choose **Start** (global button) to display the **Start Conditions** screen.

2 Choose **Masking** to display the **Masking** window.

3 Choose **Module Masking** to display the **Module Masking** window.

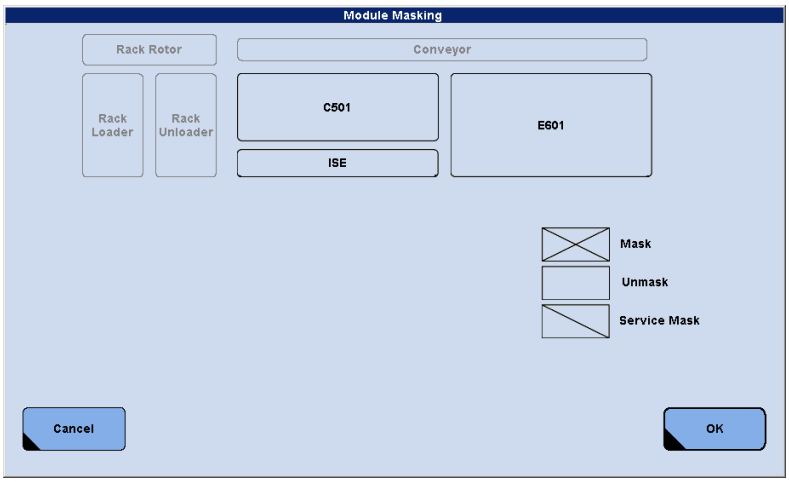


Figure C-13 Module Masking window

4 Choose the modules to be masked. When a module is masked, it appears crossed out on the display.

5 Choose **OK** to save the changes.

6 Choose **Yes** on the confirmation window.

7 Allow the module to go to standby mode. The module completes any samples assigned to it prior to masking, goes to **Sampling Stop** mode and then to standby mode.

8 You may now perform any of the maintenance procedures listed in the background maintenance table.

See *Background and parallel maintenance* on page C-34.

■

The module can be masked/unmasked when the system is in standby or operation mode.

Using maintenance pipes for background maintenance

A maintenance pipe can be performed during background maintenance on the following conditions:

- The maintenance pipe must only contain maintenance items for the masked module.
- The analyzer is in operation mode.
- The masked module is in standby

Performing parallel maintenance

You may use parallel maintenance to perform different maintenance items on different modules while the system is in the standby mode.

Pipe functions cannot be performed as parallel maintenance; you must perform all maintenance items individually.

For example, you can select maintenance item **(4) Cell Blank Measurement** on **c** 501 and maintenance item **(21) Bead Mixer Rinse** on **e** 601.

See *Background and parallel maintenance* on page C-34.

If you need to stop a maintenance procedure while the other modules are in operation, use the following steps.

Stopping background and parallel maintenance

Use the following procedure to stop background or parallel maintenance.

Do not choose **Stop** (global button) to end background maintenance. This will stop all functions on all modules.

► To stop background maintenance

1 Choose **System Overview**.

2 Select the module performing the function you want to stop.

3 Choose **Cancel Maintenance** to stop the action after confirmation.

■

List of maintenance items

The following section lists all maintenance items, on which module they can be performed, and a brief description of their function. The time period in brackets denotes the system time of the maintenance item in (min:sec).

c 501: Denotes that a function applies to both units, the photometric unit and the ISE unit.

c 501 **(ISE)**: Denotes that a function applies to the ISE unit of the **c** 501 module only.

c 501 **(P)**: Denotes that a function applies to the photometric unit of the **c** 501 module only.

For more information, see:
(1) Reset
(2) Rack Reset
(3) Photometer Check
(4) Cell Blank Measurement
(5) Incubation Water Exchange
(6) Air Purge
(7) Wash Reaction Parts
(8) Reagent Prime
(9) Cell Detergent Prime
(10) Incubator Bath Cleaning
(11) IS Bath Cleaning
(12) Sample Probe Wash
(13) Motor Off
(14) Floppy Disk Utility
(15) Parameter Read/Write
(16) Test Count Write
(17) QC Timer Reset
(18) Probe Check
(19) System Wash
(20) Reagent Probe Wash
(21) Bead Mixer Rinse
(22) E Module Reagent Wash
(23) Pipetter Air Purge
(24) Sipper Air Purge
(25) MC Preparation
(26) MC Exchange
(27) Liquid Flow Cleaning
(28) Inventory Update
(29) Manual Cleaning
(30) Pre-wash Sipper Rinse
(31) Pre-wash Sipper Air Purge
(32) Finalization
(33) Empty PC/CC Reservoir
(34) Initial Bead Mixing
(35) Reagent Capping
(36) AssayCup Discarding
(37) System Air Purge (E Module)
(38) System Prime (E Module)
(39) Change Light Source Lamp
(40) Trace Doc Export
Smart. Com Essential information upload

(1) Reset

c 501 (0:24), **e** 601 (0:40): Mechanical parts are reset to their home positions.

cu 150: Mechanical parts are reset to their home positions, all racks are transported to the unloader.

(2) Rack Reset

cu 150: Mechanical parts are reset to their home positions, all racks including STAT racks are transported to the unloader. When there is a rack for automatic QC in the rack rotor, it will remain in the rotor unless the check box (**With Automatic QC Rack**) is selected.

(3) Photometer Check

c 501 **(P)** (3:53): Photometer output is checked by measuring a water blank of cell no. 1. Perform this maintenance item daily. To view report, choose **Print** (global button) > **View**. Measurement results must be below 14000. If results are higher, check the light path, if necessary replace the photometer lamp, then perform cell blank measurement.

Before performing this maintenance item, check that the temperature of the incubator bath water is within 37 ±0.1 °C (98.6 ±0.2 °F). Depending on the ambient temperature it can take up to 30 minutes after switching on the analyzer or after maintenance item **(5) Incubation Water Exchange** for the incubator to reach the correct temperature.

(4) Cell Blank Measurement

c 501 **(P)** (19:42): Water blanks of all cells are measured. If there is a difference greater than 0.1 absorbance units in the results for one cell compared to cell no. 1, that cell number is written to the **Abnormal Cell List**. To view this report choose **Print** (global button) > **View**.

Perform this maintenance item weekly.

(5) Incubation Water Exchange

c 501 **(P)** (4:41): Incubator bath water is exchanged and EcoTergent (approx. 4 ml) is added. Perform this maintenance item daily. If the **Incubation Water Exchange Setting** check box (**Utility** > **System**) is activated, the incubator bath water is exchanged five times and approx. 8 ml EcoTergent is added. This takes 17:30 min.

See *Incubation Water Exchange Setting* on page E-363.

After this maintenance item has been performed, check that the temperature of the incubator is within 37 ±0.1 °C (98.6 ±0.2 °F) before performing maintenance item **(3) Photometer Check**. Depending on the ambient temperature it can take up to 30 minutes for the incubator to reach the correct temperature.

(6) Air Purge

c 501 (0:52): Air is purged from sample and reagent pipetters. Perform this maintenance item daily.

(7) Wash Reaction Parts

c 501 (P) (35:00): All cells and reagent probes are washed. The sample probe is washed with Sample Cleaner 1 (approx. 1 ml). The reagent probes and cells are washed with detergent from a detergent cassette (approx. 58 ml NaOH-D, application code 947).

(8) Reagent Prime

c 501 **(ISE)**: Reagents are primed according to the chosen option (IS, Ref, or All).

Options	System time	Description	Reagent consumption
IS	4:35	ISE IS is aspirated through the sipper to prime the measurement cartridges.	ISE IS: 6.6 mL ISE Ref.: 0.8 mL
Ref	2:34	ISE Ref. is aspirated through the reference cartridge to prime the reference electrode.	ISE IS: 0 mL ISE Ref.: 9.0 mL
All	6:44	Both ISE IS and ISE Ref. are primed.	ISE IS: 6.6 mL ISE Ref.: 9.8 mL

Table C-21 **c** 501 reagent prime options

e 601: If **Reagent** is selected the tubings of ProCell and CleanCell are primed and air bubbles are washed out of the system by emptying the reservoirs and refilling them. If Pre-wash Sipper is selected the PreClean tubings are primed and air bubbles are washed out of the system.

(9) Cell Detergent Prime

c 501 **(P)** (7:30)**:** Reagent lines for Cell Wash Solution I / NaOH-D and Cell wash Solution II / Acid Wash are primed (30 times); reagent lines are purged of air and cells are filled up and emptied by vacuum.

(10) Incubator Bath Cleaning

c 501 **(P):** Performs transition to incubator bath cleaning mode: The photometer lamp is switched off and the incubator bath water is automatically drained. Cleaning of ultrasonic mixers or incubator bath is possible without complete system shutdown. Choose **Continue** on the **Utility** > **Maintenance** >**Incubator Bath Cleaning** window to end the incubator bath cleaning mode; the incubator bath is automatically refilled with water and EcoTergent (approx. 4 ml).

(11) IS Bath Cleaning

c 501 **(ISE)** (1:35): The IS bath is rinsed. Perform this maintenance daily. However, this is not necessary after processing a green rack (flow path washing) because IS bath cleaning is already included in that maintenance.

(12) Sample Probe Wash

c 501: The sample probe is washed with Sample Cleaner 1. This item can be used in case of a clogged probe.

(13) Motor Off

c 501: The motors of the **c** 501 module are switched off. Use this item to manually move different parts, such as reagent gripper or reaction disk, without having to shut down the analyzer. If you open the top cover of the **c** 501 module, the motors of the module are also switched off.

For more information, see *Interlock function: Reset after stop* on page B-235.

(14) Floppy Disk Utility

Control unit: A floppy disk inserted into the floppy disk drive will be formatted after confirmation.

(15) Parameter Read/Write

Control unit: Parameter settings are read from or written to a storage medium.

(16) Test Count Write

c 501, **e** 601: Test count for all modules and measuring cells is written to a storage medium.

(17) QC Timer Reset

c 501 (P), **e** 601: Resets the control interval timer.

For example, the control interval timer is set to 10 hours. When 5 hours are left, the user can reset the timer to 10 hours.

(18) Probe Check

c 501**:** Puts the **c** 501 module in probe adjust mode: In this mode, a probe—selected in the **Probe Adjust** window—can be moved to designated positions using the maintenance key. This maintenance item should only be used by specially trained operators to verify alignment of the probe.

For more information, refer to the separate maintenance manual *Interlock function cobas* **c** 501 *with ISE.*

(19) System Wash

e 601: Combination of maintenance items **(20) Reagent Probe Wash**, **(21) Bead Mixer Rinse**, and **(22) E Module Reagent Wash** is performed as many times as specified.

(20) Reagent Probe Wash

e 601: Both the inside (by aspirating the ProbeWash solution) and outside of the reagent pipetter probe is washed as many times as specified.

(21) Bead Mixer Rinse

e 601: The microbead mixer is rinsed as many times as specified.

(22) E Module Reagent Wash

e 601: The auxiliary reagent flow paths and the reservoirs for both ProCell and CleanCell are rinsed. That is, remaining liquid is aspirated from the reservoirs and discharged to the washing stations. Then, the auxiliary reagent flow paths and reservoirs are filled with water.

The sippers aspirate liquid in the reservoirs and discharge it to the washing stations as many times as necessary to drain the whole liquid of the reservoirs.

Afterwards **(38) System Prime (E Module)** and **(32) Finalization** should be performed.

(23) Pipetter Air Purge

e 601: Sample pipetter and reagent pipetter flow paths are purged of air as many times as specified.

(24) Sipper Air Purge

e 601: Sipper flow paths are purged of air as many times as specified.

(25) MC Preparation

e 601: Measuring cells are conditioned as many times as specified.

(26) MC Exchange

e 601: Sipper flow paths are rinsed with water as many times as specified and then emptied to be prepared for a measuring cell exchange.

(27) Liquid Flow Cleaning

e 601: Sipper flow paths are washed with SysClean. Liquid flow path cleaning must be performed at least once every two weeks or after 2500 to 3000 determinations per measuring cell.

(28) Inventory Update

e 601: The number of magazines with AssayTips and AssayCups in the loading area and empty magazines in the waste area are updated.

(29) Manual Cleaning

e 601: Sample pipetter, reagent pipetter, microbeads mixer, and sippers are reset and move to positions where manual cleaning of these parts can be done. The instrument stays in the maintenance function **Manual Cleaning** until the **Stop** (global button) or **Cancel Maintenance** on **System Overview** screen is chosen.

(30) Pre-wash Sipper Rinse

e 601: Pre-wash Sippers are rinsed in the wash station as many times as specified.

(31) Pre-wash Sipper Air Purge

e 601: Pre-wash Sipper flow paths are purged of air.

(32) Finalization

e 601 (5:30): Finalization routine is carried out on sample pipetter, reagent pipetter, sipper and detection unit.

(33) Empty PC/CC Reservoir

e 601 (2:40): The liquid in the ProCell and CleanCell reservoirs is drained.

(34) Initial Bead Mixing

e 601: Microbeads are mixed in all occupied positions on the reagent rotor.

(35) Reagent Capping

e 601: All open **cobas e** packs on the reagent rotor are closed.

(36) AssayCup Discarding

e 601: All AssayCups are taken out of the incubator and discharged to the waste by the gripper.

(37) System Air Purge (E Module)

e 601: The following maintenance functions are performed:

- (23) Pipetter Air Purge
- (24) Sipper Air Purge
- (31) Pre-wash Sipper Air Purge.

(38) System Prime (E Module)

e 601: ProCell, CleanCell, and both Pre-wash lines are primed at the same time.

(39) Change Light Source Lamp

c 501 (**P**): The photometer lamp is switched off. Use this item to exchange the photometer lamp without having to shut down the analyzer.

(40) Trace Doc Export

c 501**, e** 601**:** Backup function; configuration settings and patient data (identical to *Smart. Com Essential information upload*) are exported from the flash memory of the analyzer to a selected storage medium. With software available from your Roche Diagnostics representative this file can be archived and viewed on external personal computers and provides traceability for test results.

It is recommended to perform this maintenance item every day, before any data has been deleted. It can be performed manually or in a maintenance pipe.

For more information, see *Data storage* on page B-244.

Smart. Com Essential information upload

c 501**, e** 601**:** Backup function; configuration settings and patient data are uploaded from the flash memory of the analyzer to the **cobas** link PC. The five most recent backups are stored on the **cobas** link and allow for restoring parameter backup files to the flash memory of the analyzer.

It is recommended to perform this maintenance item every day. This maintenance item can only be performed in a maintenance pipe. Therefore it can only be selected on the **Edit Pipe** window under **Utility** >**System** >**Pipe Setting** > **Edit**.

For more information, see:
Defining and editing maintenance pipes on page C-11
Recommended maintenance pipes on page C-32

List of maintenance checks

The following section lists all maintenance checks, on which module they can be performed, and a brief description of their function.

(1) Check Disk

(2) ISE Check

(3) Mechanism Check

(4) Sample Barcode Reader Check

(5) Reagent Barcode Reader Check

(6) Cassette Loading Check

(7) Cuvette Mixing

(8) Reagent Short Sensor Check

(9) Sample Pipetting Check

(10) Reagent Pipetting Check

(11) Cap Opener Check

(12) Bead Mixer Check

(13) Gripper Check

(14) Magazine Exchange Check

(15) Sipper Check

(16) Pre-wash Probe Check

(17) Pre-wash Gripper Check

(1) Check Disk

Files on hard disk, floppy disk, USB storage device, or DVD disk are checked by the control unit. A result list is available in the print buffer afterwards. This list is not automatically printed. The disk check can also be used to save a log file (Backup data file) and to determine the software version.

(2) ISE Check

c 501**(ISE)**: The electrode output of ISE cartridges ($Cl^-/K^+/Na^+$ and ISE reference cartridge) is measured with ISE IS and a listing of EMF values is printed out.

(3) Mechanism Check

The option **All** performs a functional check of mechanical parts of the entire sample line and each module. Make sure to place some racks in the rack loader.

The option **Rack Sampler** performs a functional check of mechanical parts of the rack sampler unit. Make sure to place some racks in the rack loader.

The option **Analyze Module** performs a mechanical check for selected modules according to entered number of cycles.

If the check box **With Photo Interrupter** check is selected, the system checks automatically all relevant photo coupler sensors during this maintenance function. Only the defective sensors are shown in the print view screen.

Choose **S. Stop** to end this maintenance check and to move all racks to the unloader.

(4) Sample Barcode Reader Check

The barcode on a sample tube is scanned. After pressing **Stop**, the data is displayed in the print preview for verification. There is no automatic printout. After pressing **Stop** a system reset has to be performed.

c 501**:** Check the function of the sample barcode reader:

Set a rack with barcoded tubes in the rack loader and start the sample barcode reader check.

The rack moves first to the barcode reader in the rack feeder line. After reading the relevant positions the rack moves to the barcode reader in the sampling line of the selected modules.

According to the selected cycles the rack moves to the unloader or back to the rack feeder line.

The reading results are shown in the print view screen.

(5) Reagent Barcode Reader Check

The reagent barcode reader is checked according to input cycle (minimum is 5 cycles).

c 501: After starting the **Reagent Barcode Reader Check** a reagent cassette must be inserted in the cassette loading port. The gripper retracts the cassette automatically and the barcode reader reads in the barcode information on the cassette 5 times. Finally the results are shown in the print view screen. The cassette is ejected to the loading port and can be removed.

e 601: The barcodes of the loaded **cobas e** packs are read.

(6) Cassette Loading Check

c 501: A check for cassette loading, gripper and piercer movement is performed according to input cycle (minimum: 5 cycles).

(7) Cuvette Mixing

c 501: Performs a functional check on the ultrasonic mixers (1:32)—optionally with cell wash (system time with cell wash: 19:26).

The reagent probe pipettes deionized water in the corresponding cell (cuvette) for R1, R2 and R3 mixer. Then the cuvette turns to the mixing position and ultra sonic mixing is executed. The proper operation of the corresponding mixer can be checked visually—the water in the cuvette is vibrating when the mixer is operating.

(8) Reagent Short Sensor Check

e 601: The sensors in the lines of the PreClean, ProCell and CleanCell bottles will be checked.

(9) Sample Pipetting Check

e 601**:** The movement of the sample pipetter is checked and its liquid level detection function.

(10) Reagent Pipetting Check

e 601**:** The movement of the reagent pipetters is checked.

(11) Cap Opener Check

e 601**:** The movement of the cap opener is checked.

(12) Bead Mixer Check

e 601**:** The movement of the microbead mixer is checked.

(13) Gripper Check

e 601**:** The movement of the gripper and its tip and AssayCup handling function is checked.

(14) Magazine Exchange Check

e 601**:** The movement of the magazine exchange is checked.

(15) Sipper Check

e 601**:** The movement of the sippers and their liquid level detection function is checked.

(16) Pre-wash Probe Check

e 601**:** The movement and function of the Pre-wash sipper is checked. The Pre-wash sipper and syringe will aspirate and discharge PreClean during this procedure.

Manually add cups to the separation stations.

(17) Pre-wash Gripper Check

e 601**:** The movement of the Pre-wash Gripper is checked as well as its AssayCup handling function.

Make sure to place AssayCups on the following positions before you start this procedure:

- Pre-wash Gripper position on the incubator (position 6)
- Vortex mixer position
- First position in the Pre-wash station

Maintenance cu 150

This chapter describes the maintenance actions required for correct and efficient running of the **cu** 150. The schedule of required periodic maintenance actions (daily, weekly, monthly…) is provided as well as maintenance actions that are performed as needed.

In this chapter *Chapter* 16

Maintenance schedule C-49
Daily maintenance C-50
Emptying and cleaning the concentrated waste tank C-50
Monthly maintenance C-53
Cleaning the water tank C-53
Cleaning the filter of the rack sampler unit C-57
Every six months maintenance C-58
Cleaning the inlet water filter C-58
Cleaning the cooling fans C-60
As needed C-61
Cleaning instrument surfaces C-61

Maintenance schedule

The intervals for maintenance and checkup recommended in this document are independent of the system operation time unless otherwise noted (e g. maintenance actions which are based on test count or time).

PO	Power OFF (shut down status)
SB	Stand by

	Procedure	Mode	Operator time (min)	System time (min)	Page
Daily	Emptying and cleaning the concentrated waste tank	PO	2		C-50
Monthly	Cleaning the water tank	PO	5		C-53
	Cleaning the filter of the rack sampler unit	SB/PO	5		C-57
Every 6 months	Cleaning the inlet water filter	PO	5		C-58
	Cleaning the cooling fans	PO	5		C-60
As needed	Cleaning instrument surfaces	SB/PO	5		C-61

Table C-22 Maintenance schedule **cu** 150

Create a maintenance schedule, which is customized to your laboratory's individual requirements. We recommend letting the analyzer's software remind the operator of all periodic maintenance tasks. You can do this by configuring maintenance types (from **Utility** > **System** (**Page 2/4**) > **Maintenance Setting**). Within a maintenance type, you can assign maintenance intervals (**Period**) and warning levels to each maintenance item and maintenance pipe.

For more information on scheduling maintenance tasks, see *Maintenance types—scheduling and tracking maintenance items* on page C-9.

Daily maintenance

In this section you find all the maintenance for the **cu** 150 module that must be performed every day.

Emptying and cleaning the concentrated waste tank

The system issues an alarm if the concentrated waste tank requires emptying. To prevent disruption to the daily routine, empty the concentrated waste tank at the end of the day before shutdown and clean the tank if necessary.

Operator time approximately 2 minutes

Materials required
- ☐ Water
- ☐ Laboratory disinfectant (no bleach)
- ☐ Paper towels

⚠ CAUTION

Harmful fumes due to combination of bleach with content of the waste tank

The combination of bleach with the content of the waste tank can cause potentially harmful fumes.

- Do not use bleach to clean the waste tank.

Do not use alcohol or bleach to clean the waste tank as this may damage the waste tank.

► To empty and clean the concentrated waste tank

1 Locate the concentrated waste tank at the rear of the rack sampler unit.

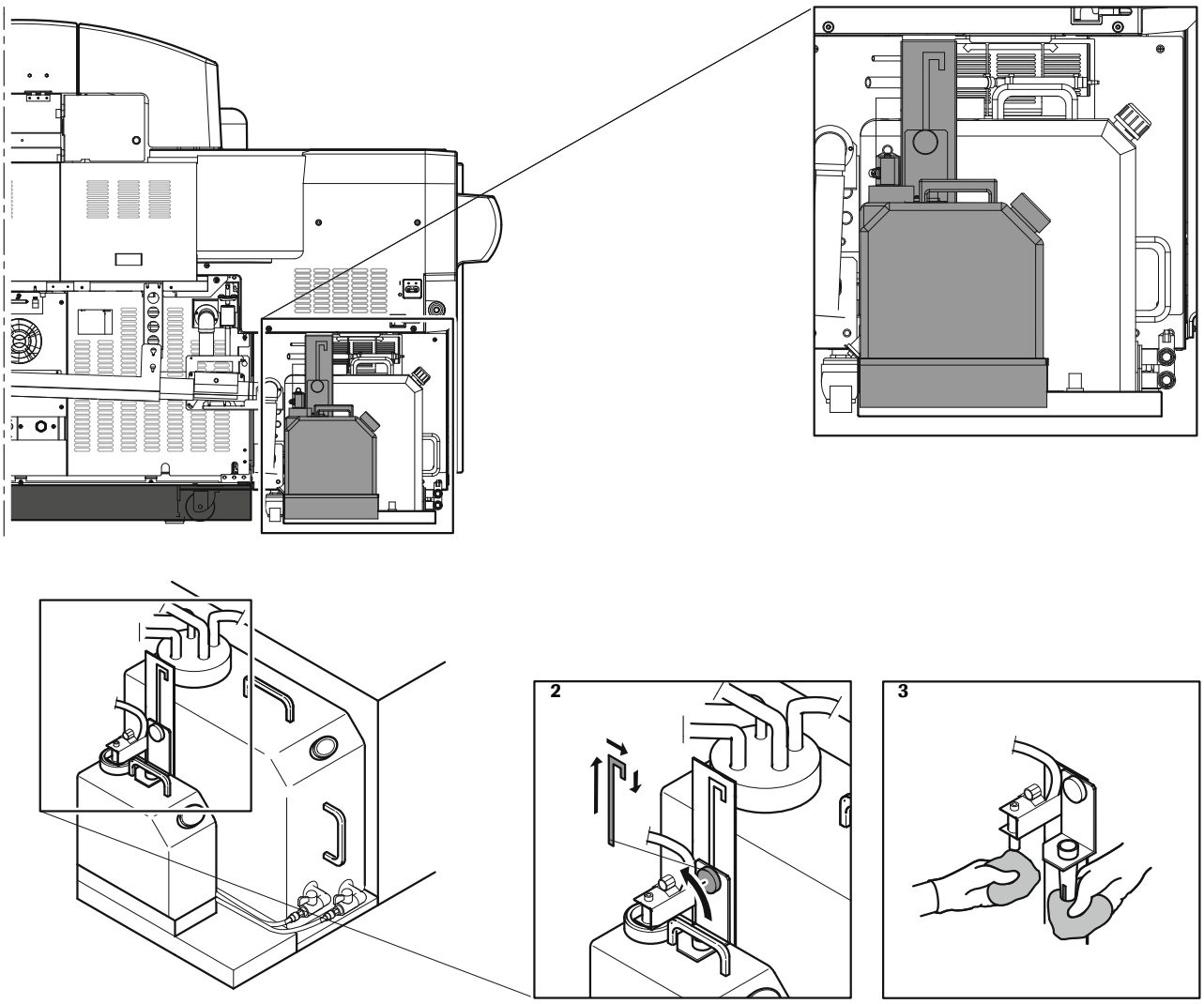


Figure C-14 Emptying and cleaning the concentrated waste tank

2 Lift the liquid level sensor assembly from the waste tank and secure it on the notch.

3 Clean the concentrated waste drain and the liquid level sensor and place paper towels below them.

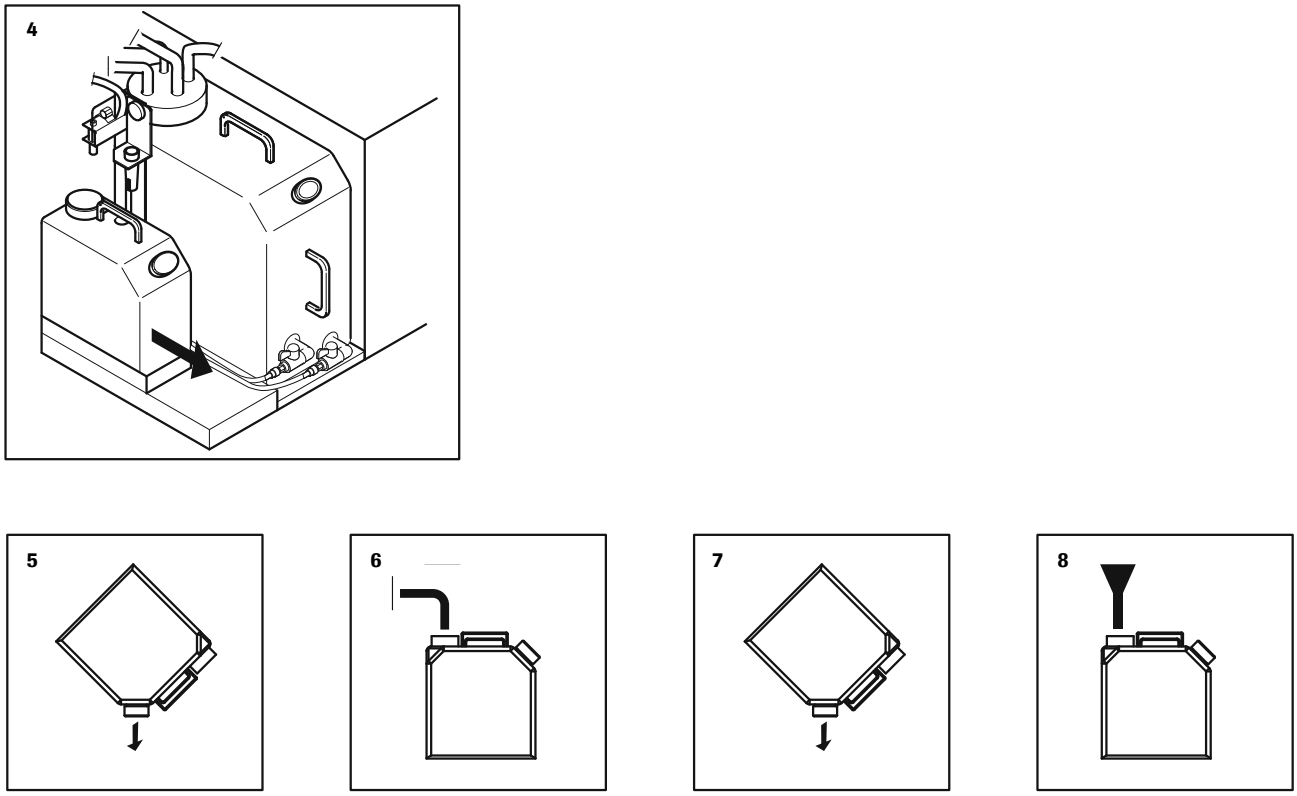


Figure C-15 Emptying and cleaning the concentrated waste tank

4 Remove the waste tank.

5 Dispose of the contents of the waste tank according to your laboratory's biohazardous waste disposal regulations.

6 Rinse the waste tank thoroughly with water

7 Dispose of the rinse water in the same manner.

8 Prepare the disinfectant according to the manufacturers' instructions and pour the disinfectant into the waste tank.

9 Place the waste tank back in its original position.

10 Place the liquid level sensor assembly back in the waste tank.

11 Dispose of the paper towels according to your laboratory's biohazardous waste disposal regulations and disinfect the area where you were working.

■

Monthly maintenance

In this section, you find all the maintenance for the **cu** 150 that must be performed at least once a month.

Cleaning the water tank

Contamination inside the tank will result in contamination of the entire flow path and adversely affect all measurements. Check the water tank at least once a month and clean the tank if necessary.

Operator time approximately 5 minutes

Materials required
- ☐ 0.5% sodium hypochlorite solution
- ☐ Deionized water
- ☐ Lint-free gauze pads
- ☐ Paper towels
- ☐ Brush

► To disconnect the water tank

1 Put the analyzer in shutdown status.

See *To shutdown the analyzer* on page C-6.

2 Locate the water tank at the rear of the rack sampler unit.

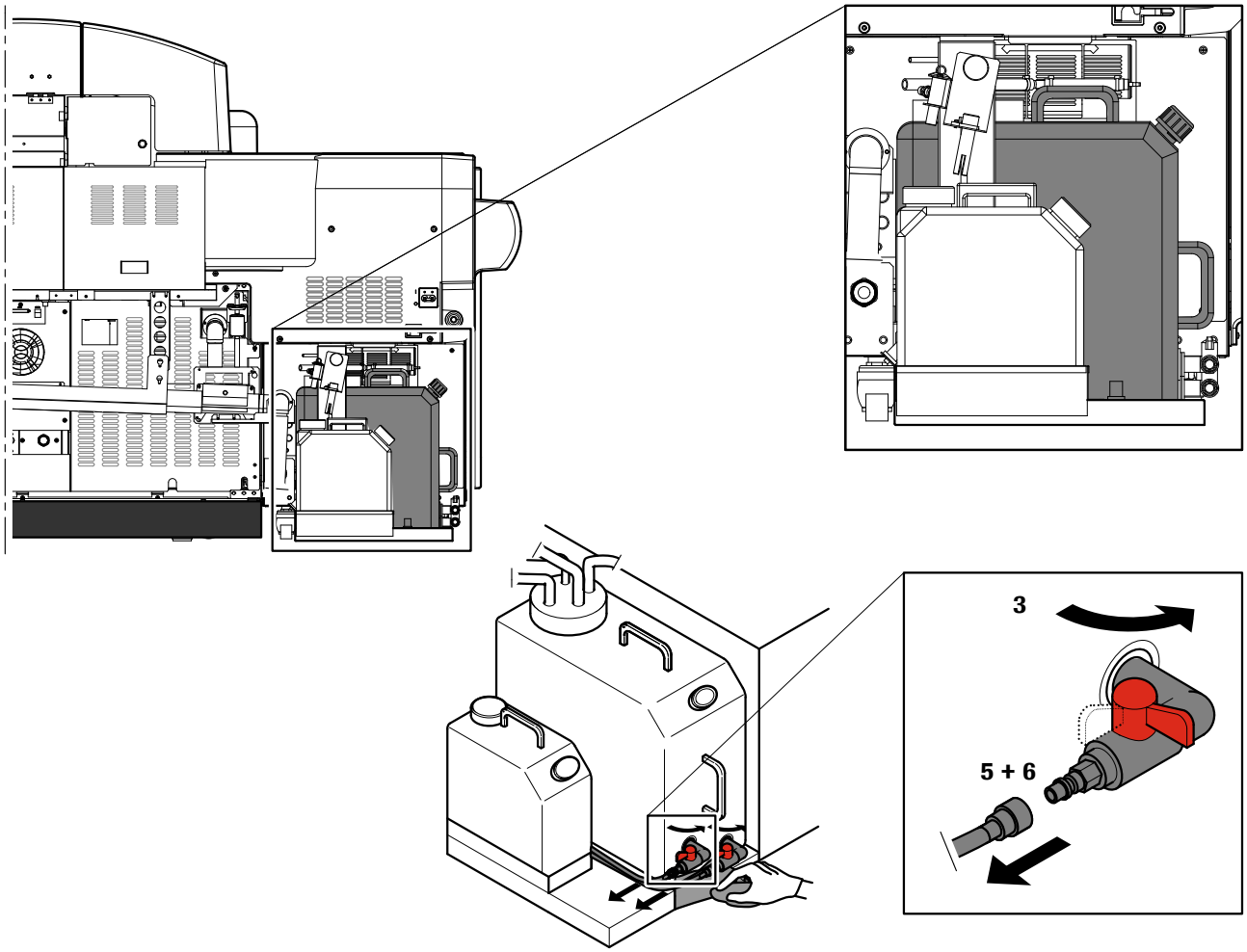


Figure C-16 Disconnecting the two joints of the water tank

3 Close the taps at the outlet of the water tank.

4 Place paper towels under the hose unit to absorb extra water.

5 Disconnect the quick release connector by rotating the release collar until it lines up with its key.

6 Pull back the spring-loaded collar to separate the water hose from the tank.

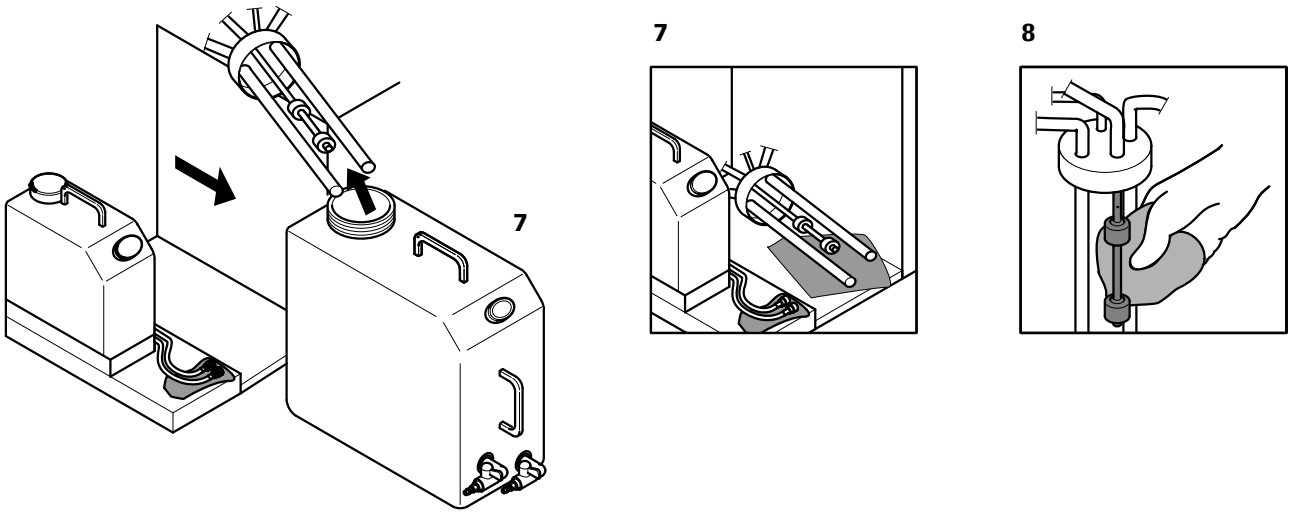


Figure C-17 Cleaning the liquid level sensor assembly of the water tank

CAUTION! The water tank can be heavy. If the tank is too heavy, pour out sufficient water until the tank becomes light to carry.

7 Pulling the water tank sideways, remove the liquid level sensor assembly from the tank and place it on a paper towel, then empty the water from the tank.

8 Wipe the liquid level sensor assembly with gauze pads soaked with deionized water.

9 Rinse the water tank thoroughly with deionized water three times.

If the water tank is considerably contaminated, follow the procedure below: *To thoroughly clean the water tank*. Otherwise, proceed as follows:

10 Fill the tank at least 1/3 full with deionized water.

11 Reattach the liquid level sensor assembly and place the tank to its original position.

12 Reconnect the water hose to the water tank and open the taps.

13 Ensure main water supply is on.

■

► To thoroughly clean the water tank

1. Rinse the tank thoroughly with 0.5% sodium hypochlorite solution. For thorough cleaning use a brush to clean the interior surface. Then wash with tap water to eliminate the detergent.
2. Rinse the tank thoroughly with deionized water 3 times.
3. Fill the tank at least 1/3 full with deionized water.
4. Reattach the liquid level assembly and place the tank to its original position.
5. Reconnect the water hose to the water tank and open the taps.
6. Ensure main water supply is on.
7. Switch on the analyzer.

■

Slip hazard due to leaking water

If the fittings of the water tank are not connected properly, water may leak.

- Ensure that all joints are connected properly.

Cleaning the filter of the rack sampler unit

Clean the filter at the rear of the rack sampler unit at least once a month to prevent dust or dirt accumulation.

Operator time approximately 5 minutes

Materials required ☐ Vacuum cleaner

► To clean the filter of the rack sampler unit

1 Put the analyzer in shutdown or standby status.

👁 See *To shutdown the analyzer* on page C-6.

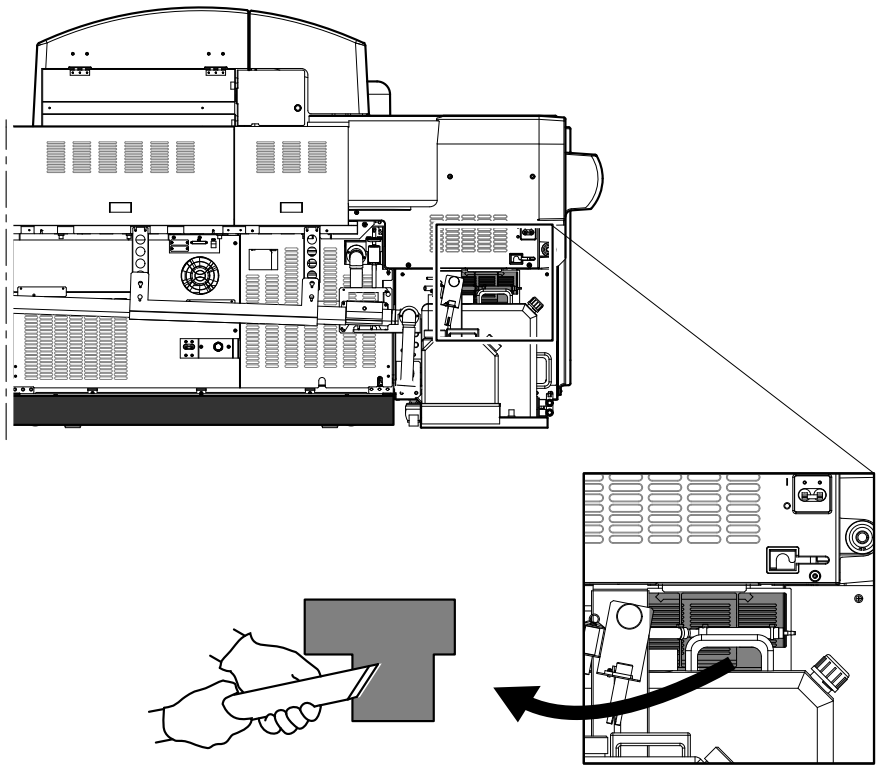


Figure C–18 Cleaning filter of rack sampler unit

2 Remove the filter of the rack sampler unit.

3 Vacuum dirt and other debris from the filter of the rack sampler unit.

4 Reattach the filter of the rack sampler unit.

5 Switch on the analyzer.

■

Every six months maintenance

In this section, you find all the maintenance for the **cu** 150 that must be performed at least once every six months.

This section discusses the following maintenance actions:
Cleaning the inlet water filter on page C-58
Cleaning the cooling fans on page C-60

Cleaning the inlet water filter

Clean the inlet water filter at least once every six months to prevent blockages of the water system.

Operator time approximately 5 minutes

Materials required
- ☐ Inlet water filter (in case replacement is required)
- ☐ Beaker, 500 mL
- ☐ Deionized water

► To clean the inlet water filter

1 Put the analyzer in shutdown status.

2 Close the water tap and halt the supply of water from the external deionized water supply.

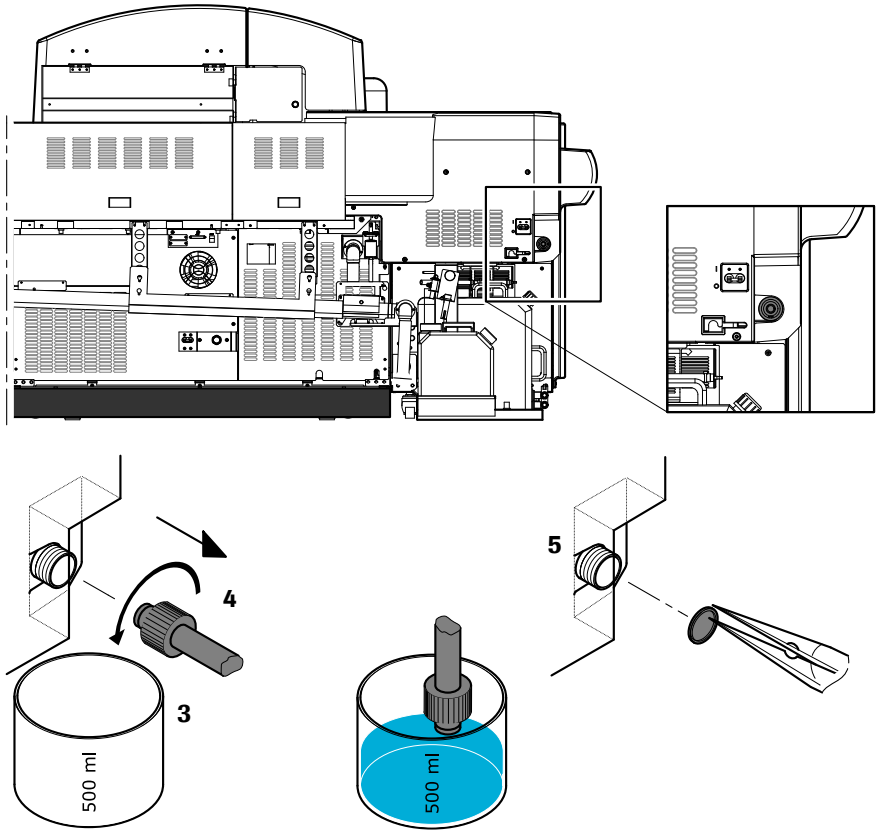


Figure C-19 Disconnecting inlet water hose and removing inlet water filter

3 Place a 500 mL beaker (or a similar type container) beneath the inlet water manifold.

4 Turn the knurled ring on the water filter cap counterclockwise and disconnect the inlet water hose.

5 Remove the water filter and place the hose in the beaker. Be careful not to tip the beaker.

6 Clean the filter thoroughly with deionized water, then reinstall the filter.

If necessary, replace the inlet water filter.

After cleaning, tighten the filter cap securely and make sure there is no water leakage.

NOTICE! Instrument damage due to loose tube sockets. Water leakage may occur. Reconnect the inlet water hose to the inlet water manifold accurately.

7 Reconnect the inlet water hose to the inlet water manifold.

8 Ensure the water supply is on, before you start up the analyzer again.

■

Cleaning the cooling fans

Clean the cooling fans at the rear of the **c** 501 and **e** 601 modules to remove dust and dirt.

Operator time approximately 5 minutes

Materials required
- ☐ Vacuum cleaner
- ☐ Brush

► To clean a cooling fan

1 Put the analyzer in shutdown status.

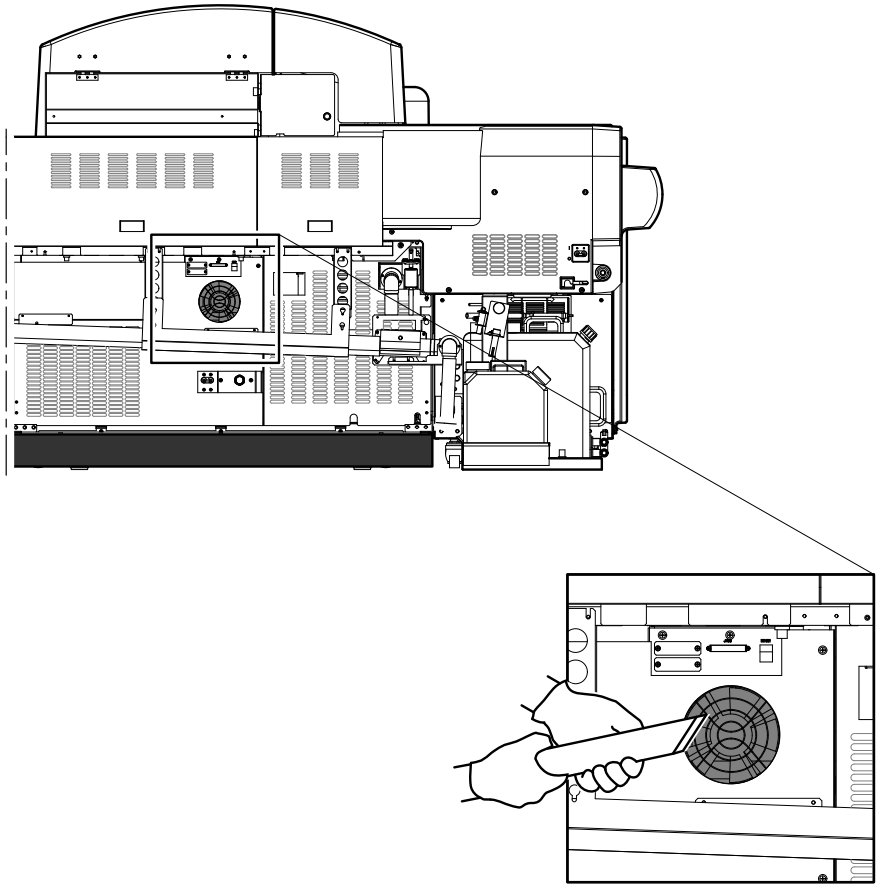


Figure C-20 Cleaning the cooling fans

2 Vacuum or brush dust, dirt, and other debris from all cooling fans on the back of each module.

3 Start up the analyzer.

■

As needed

In this section, you find all the maintenance for **cu** 150 that must be performed as needed and are not subject to a regular time schedule.

Cleaning instrument surfaces

Spills on the instrument surface could be potentially biohazardous and damage the surface.

Operator time approximately 5 minutes

Materials required
- ☐ Cloth or paper towels
- ☐ Laboratory disinfectant (no alcohol or bleach)

► To clean instrument surfaces

1 Put the analyzer in shutdown status or in standby.

👁 See *To shutdown the analyzer* on page C-6.

2 Clean the module surfaces using a cloth or paper towel moistened with disinfectant.

Clean up all spills immediately. Use this procedure to ensure that surfaces are clean.

■

As needed

Maintenance c 501 with ISE

This chapter describes the maintenance actions required for correct and efficient running of the **c** 501 module. The maintenance of both ISE unit and photometric unit is discussed. The schedule of required periodic maintenance actions (daily, weekly, monthly…) is provided as well as maintenance actions that are performed as needed.

Further maintenance actions, that can only be performed by specially trained operators, are required for a correct and efficient running of the **c** 501 module. These maintenance actions are described in a separate manual: *Interlock function cobas* **c** 501 *with ISE.*

In this chapter *Chapter* 17

Maintenance schedule C-65
Periodic replacement of parts C-67
Daily maintenance C-68
Processing green wash rack C-69
Preparing the wash rack and checking the number of cycles C-70
At the end of analysis each day C-71
During a continuous 24-hour shift C-71
Cleaning sample probe, reagent probes, ISE probe and ISE sipper nozzle C-73
Cleaning cell rinse nozzles C-75
Cleaning the drain port for high concentrated waste C-76
Weekly maintenance C-77
Cleaning the reaction system C-77
Cleaning the cell covers C-79
Cleaning the rinse stations C-81
Removing and manually cleaning the IS bath C-83
Monthly maintenance C-84
Cleaning the ISE Ref. (KCl) aspiration filter C-84
Replacing reaction cells C-86
Cleaning the incubator bath C-88
Cleaning the detergent aspiration filters C-94
Cleaning the filters behind the front doors C-96
Every three months maintenance C-98
Cleaning the ultrasonic mixers C-98
Every six months maintenance C-101
Replacing the photometer lamp C-101

As needed maintenance C-106
Cleaning the ISE Ref. (KCl) aspiration filter C-106
Cleaning the detergent aspiration filters C-106
Replacing nozzle tips on cell rinse nozzles C-106
Cleaning the ultrasonic mixers C-108
Replacing the photometer lamp C-108
Draining the vacuum tank C-109
Cleaning instrument surfaces C-110
Extended Power OFF procedures C-111
Power OFF 1 C-111
Power OFF 2 C-112
Power ON procedures (after Extended Power OFF) C-112

Maintenance schedule

The intervals for maintenance and checkup recommended in this document are independent of the system operation time unless otherwise noted (e g. maintenance actions which are based on test count or time).

PO	Power OFF
SB	Stand by
CIB	Cleaning Incubator Bath
CLSL	Change Light Source Lamp

Interval	Procedure	Mode	Operator time (min)	System time (min)	Page
Daily	Processing green wash rack		5	15[(a)]	C-69
	Cleaning sample probe, reagent probes, ISE probe and ISE sipper nozzle	SB/PO	2		C-73
	Cleaning cell rinse nozzles	SB/PO	2		C-75
	Cleaning the drain port for high concentrated waste	SB/PO	1		C-76
Weekly	Cleaning the reaction system	SB	2	55	C-77
	Cleaning the cell covers	SB/PO	5		C-79
	Cleaning the rinse stations	SB/PO	5		C-81
	Removing and manually cleaning the IS bath	SB/PO	5		C-83
Monthly	Cleaning the ISE Ref. (KCl) aspiration filter	SB/PO	5	3	C-84
	Replacing reaction cells	CIB/SB/PO	10	55	C-86
	Cleaning the incubator bath	CIB/PO	15	25	C-88
	Cleaning the detergent aspiration filters	SB/PO	5	7	C-94
	Cleaning the filters behind the front doors	SB/PO	10		C-96
Every 3 months	Cleaning the ultrasonic mixers[(c)]	CIB	6	7	C-98
Every 6 months[(b)]	Replacing the photometer lamp[(d)]	CLSL/PO	5	20	C-101
As needed[(b)]	Cleaning the ISE Ref. (KCl) aspiration filter	SB/PO	5	3	C-106
	Cleaning the detergent aspiration filters	SB/PO	5	7	C-106
	Replacing nozzle tips on cell rinse nozzles	SB/PO	6		C-106
	Replacing the photometer lamp[(d)]	CLSL/PO	5	20	C-108
	Cleaning the ultrasonic mixers[(c)]	CIB	6	7	C-108
	Draining the vacuum tank	SB/PO	5		C-109
	Cleaning instrument surfaces	SB/PO	5		C-110

Table C-23 Maintenance schedule **c** 501

(a) When **Green Rack during Operation** is enabled for a 24 hour shift

(b) All maintenance actions described as 6 monthly or as needed can be covered by appropriate service contract actions.

(c) Every 3 months or after 225.000 tests (whatever comes first)

(d) Every 6 months, after 750 hours or if the photometer check value exceeds 14000 (whatever comes first)

Create a maintenance schedule, which is customized to your laboratory's individual requirements. We recommend letting the analyzer's software remind the operator of all periodic maintenance tasks. You can do this by configuring maintenance types (from **Utility** > **System** (**Page 2/4**) > **Maintenance Setting**). Within a maintenance type, you can assign maintenance intervals (**Period**) and warning levels to each maintenance item and maintenance pipe.

For more information on scheduling maintenance tasks, see *Maintenance types—scheduling and tracking maintenance items* on page C-9.

For more information about the maintenance actions required in certain intervals, see:
Daily maintenance on page C-68
Weekly maintenance on page C-77
Monthly maintenance on page C-84
Every six months maintenance on page C-101
As needed maintenance on page C-106

Periodic replacement of parts

Some parts require periodic replacement for preventive maintenance. Replace these parts regularly and in accordance with your workload and the recommendations given in this document.

ISE unit

Item	2 months	3 months	6 months	As needed	Reference
ISE measuring cartridges[(a)(b)] (Na^+, K^+, Cl^-)	✗			✗	(a)
ISE reference cartridge[(a)]			✗		(a)
ISE sipper tubing[(a)]		✗		✗	(a)
ISE pinch valve tubing[(a)]		✗		✗	(a)
Syringe seals of ISE pipetter and ISE sipper[(c)]				✗	(c)

Table C-24 Periodic replacement of parts for **c** 501 ISE unit

(a) Can only be done by specially trained operators

(b) Every 2 months or after 9000 samples (whatever comes first)

(c) Can only be done by a Roche service representative

Photometric unit

Item	Monthly	3 months	6 months	As needed	Reference
Reaction cells	✗				C-86
Photometer lamp[(a)]			✗	✗	C-101
Syringe seals of sample probe and reagent probes[(b)(c)]			✗	✗	(c)

Table C-25 Periodic replacement of parts for **c** 501 photometric unit

(a) Every 6 months or after 750 hours, or if the photometer check exceeds 14000 (whatever comes first)

(b) Every 6 months or after 225.000 tests (whatever comes first)

(c) Can only be done by a Roche service representative

Incorrect results due to improper spare parts

For proper instrument care use only original spare parts provided by Roche Diagnostics.

- The necessary spare parts are listed in the description of the corresponding maintenance action.
- To order spare parts, please contact your Roche service representative.

Daily maintenance

In this section, you find all the maintenance for the **c** 501 module that must be performed every day.

This section discusses the following maintenance actions:
Processing green wash rack on page C-69
Cleaning sample probe, reagent probes, ISE probe and ISE sipper nozzle on page C-73
Cleaning cell rinse nozzles on page C-75
Cleaning the drain port for high concentrated waste on page C-76
Cleaning instrument surfaces on page C-110

Contamination of flow paths or pipetter probes may cause incorrect measurement results or blockages. Therefore, make sure to regularly perform the stated maintenance procedures.

Processing green wash rack

A green wash rack containing detergents and Activator must be processed once every 24 hours as described below.

Normally the green wash rack is processed at the end of analysis each day.

See *At the end of analysis each day* on page C-71.

If your **cobas** 6000 analyzer operates continuously during a 24-hour shift, the green wash rack must be processed once every 24 hours.

See *During a continuous 24-hour shift* on page C-71.

Operator time approximately 5 minutes

System time approximately 15 minutes during a 24-hour shift

Materials required

- ☐ Green rack (wash rack)
- ☐ Sample Cleaner 1, 400 µL (5 cycles) per **c** 501 module
- ☐ SysClean, 300 µL (15 cycles) per **c** 501 module
- ☐ Activator, 300 µL (15 cycles) per **c** 501 module

ISE reagent consumption

Approximately 18 mL internal standard (ISE IS)

Approximately 7 mL diluent (ISE Dil.)

Approximately 2 mL reference electrode solution (ISE Ref.)

⚠ CAUTION

Incorrect patient results due to shortage of ISE conditioning solution (Activator) or ISE cleaning solution (SysClean)

If the amount of Activator or SysClean is not sufficient or the sample cup containing the Activator or SysClean is missing or in an incorrect position, the conditioning or cleaning of the ISE cannot be completed.

- Fill a sufficient amount of Activator and SysClean into sample cups.
- Place the sample cups in the correct position of the green wash rack.
- If an alarm due to insufficient volume of these solutions is issued, all ISE samples measured after the alarm must be rerun.

⚠ CAUTION

Incorrect results due to wrong calibration

After processing a green wash rack all ISE tests must be calibrated.

- P-mask the ISE before running the green wash rack during operation.

For information about P-masking, see *T-masking and P-masking* on page B-237.

- Do not load samples with ISE requests before you have checked the calibration and QC results for ISE.

If the processing of the green wash rack is interrupted for some reason, perform the following maintenance items:

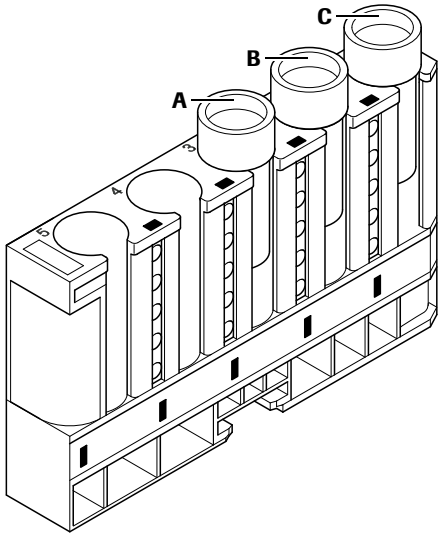
- **(7) Wash Reaction Parts**
- **(8) Reagent Prime** (All)

Preparing the wash rack and checking the number of cycles

This section describes how to prepare the wash rack.

► To prepare the wash rack

1 Place sample cups at positions 1 to 3 on a green rack (wash rack) and fill suitable amounts of Sample Cleaner 1, ISE cleaning solution (SysClean), and Activator into the sample cups as shown in the figure below.



A Activator (for conditioning) **B** SysClean **C** Sample Cleaner 1

Figure C-21 Green rack with reagents for daily ISE maintenance

- Position 1: Sample Cleaner 1, 400 µL (5 cycles) per **c** 501 module
- Position 2: ISE cleaning solution (SysClean), 300 µL (15 cycles) per **c** 501 module
- Position 3: Activator 300 µL (15 cycles) per **c** 501 module

Unless sample cups are positioned as instructed, neither sampling nor rinsing will be conducted.

2 Check the number of cycles for detergent pipetting:

- Choose **Utility** > **System**
- If necessary, change the number of cycles for both Photometric and ISE under **Wash Rack Sampling** (recommended are 5 cycles for Photometric and 15 for ISE).
- Choose **OK** to save the settings.

■

At the end of analysis each day

This section describes how to clean sample flow paths and ISE electrodes.

► To clean sample flow paths and ISE electrodes

1 Place the wash rack on the rack loader.

👁 For more information, see *To prepare the wash rack* on page C-70.

2 Choose **Start** (global button) and **Start** on the **Start Conditions** screen.

If the analyzer is already in operational status, skip this step.

3 Perform a full calibration of the ISE unit.

👁 For details on how to calibrate the ISE unit, see *Requesting and cancelling calibrations manually* on page B-167.

■

For labs not running 24 hours per day, Roche Diagnostics recommends performing the cleaning of the flow paths and conditioning of the electrodes within a sleep pipe. Then the system will go to sleep mode after the sleep pipe with green wash rack is performed.

👁 See *Sleep Pipe function with green wash rack* on page C-17.

During a continuous 24-hour shift

The analyzer offers a function to process a green wash rack in operation during a continuous 24-hour shift.

The **Green Rack during Operation** function is activated under **Utility** > **System** (**Page 3⁄4**) > **Rack Delivery**.

👁 See *Green Rack during Operation* on page B-286.

Notes for working with the Green Rack during Operation function

- The analyzer must not be in standby to process a green wash rack when this function is activated.
- Since the analyzer is still processing samples, it is possible to load any other rack together with the green wash rack. In this case only photometric and immunological tests are processed on the **c** 501 module or the **e** 601 module.
- Therefore during processing of the green wash rack do not load any sample with ISE requests because ISE tests are P-masked. If you load samples with ISE requests, the ISE requests cannot be processed until the green wash rack is finished.
- Samples with open ISE requests that were registered before masking the ISE tests will be unloaded after masking the ISE tests. You have to reload these samples after processing the green wash rack.
- It is recommended to process the green wash rack immediately before your periodic calibration during a continuous 24-hour shift.

► To process a green wash rack on a analyzer with one c 501 module

1 P-mask the ISE tests on the **Masking** window (**Start** (global button) > **Masking**).

2 Request a full calibration for all ISE tests on the **Calibration Status** screen.

👁 See *Requesting and cancelling calibrations manually* on page B-167.

3 Place the racks in the following sequence on the rack loader:

- Green wash rack.

👁 For more information, see *To prepare the wash rack* on page C-70.

- Calibrator rack containing the ISE calibrators.
- QC rack containing the QCs for ISE tests.

4 Choose **Start** (global button) and **Start** on the **Start Conditions** screen.

5 Check the results for calibration and QC.

6 If the analyzer has generated a valid calibration and the QC results are okay, unmask the ISE tests.

■

The analyzer is ready to process routine samples.

► To process a green wash rack on a analyzer with two c 501modules

1 P-mask the ISE tests for both **c** 501 modules on the **Masking** window (**Start** (global button) > **Masking**).

2 Request a full calibration for both **c** 501 modules for all ISE tests on the **Calibration Status** screen.

👁 See *Requesting and cancelling calibrations manually* on page B-167.

3 Place the green wash rack on the rack loader.

👁 For more information, see *To prepare the wash rack* on page C-70.

4 Choose **Start** (global button) and **Start** on the **Start Conditions** screen.

5 Wait until the green wash rack is in the rack unloader.

- Load a calibrator rack containing the ISE calibrators.
- Load a QC rack containing the QCs for ISE tests.

6 Choose **Start** (global button) and **Start** on the **Start Conditions** screen.

7 Check the results for calibration and QC.

8 If the analyzer has generated a valid calibration and the QC results are okay, unmask the ISE tests.

■

The analyzer is ready to process routine samples.



If you load the ISE calibrator and QC racks before the green wash rack is in the rack unloader, the green wash rack is processed on the first **c** 501 module. The calibrator and QC racks are processed on the second **c** 501 module previous to the green wash rack.

The thus obtained calibration is no longer valid, after the green wash rack has been processed on the second **c** 501 module.

Cleaning sample probe, reagent probes, ISE probe and ISE sipper nozzle

At the end of analysis each day, clean the outside of the pipetter probes (sample probe, reagent probes, ISE probe) and of the ISE sipper to remove residual solution and precipitation. This is a combined maintenance procedure for both ISE and photometric unit.

When sample aspiration error occurs frequently or if an alarm for blockages of the sample probe occurs and is not reset after cleaning (maintenance item **(12) Sample Probe Wash**), the sample probe must be detached and blockages must be eliminated.

Pipetter probes must be replaced, when they are bent or damaged. Detaching the sample probe and elimination of sample blockages must only be done by specially trained operators. Positional adjustment is required after reattaching the probe.

For more information refer to the separate maintenance manual *Interlock function cobas c 501 with ISE.*

Operator time approximately 2 minutes

Materials required
- ☐ Alcohol (e.g. isopropyl alcohol or ethanol)
- ☐ Lint-free gauze pads

Damage to the probes

Do not bend or damage the lower end of the probes during cleaning. Move the arm gently. Do not move it up and down.

► To clean the outside of sample probe, reagent probes, ISE probe and ISE sipper nozzle

1. Put the analyzer in shutdown status or the module in standby.
2. Unlock and open the top cover of the module.

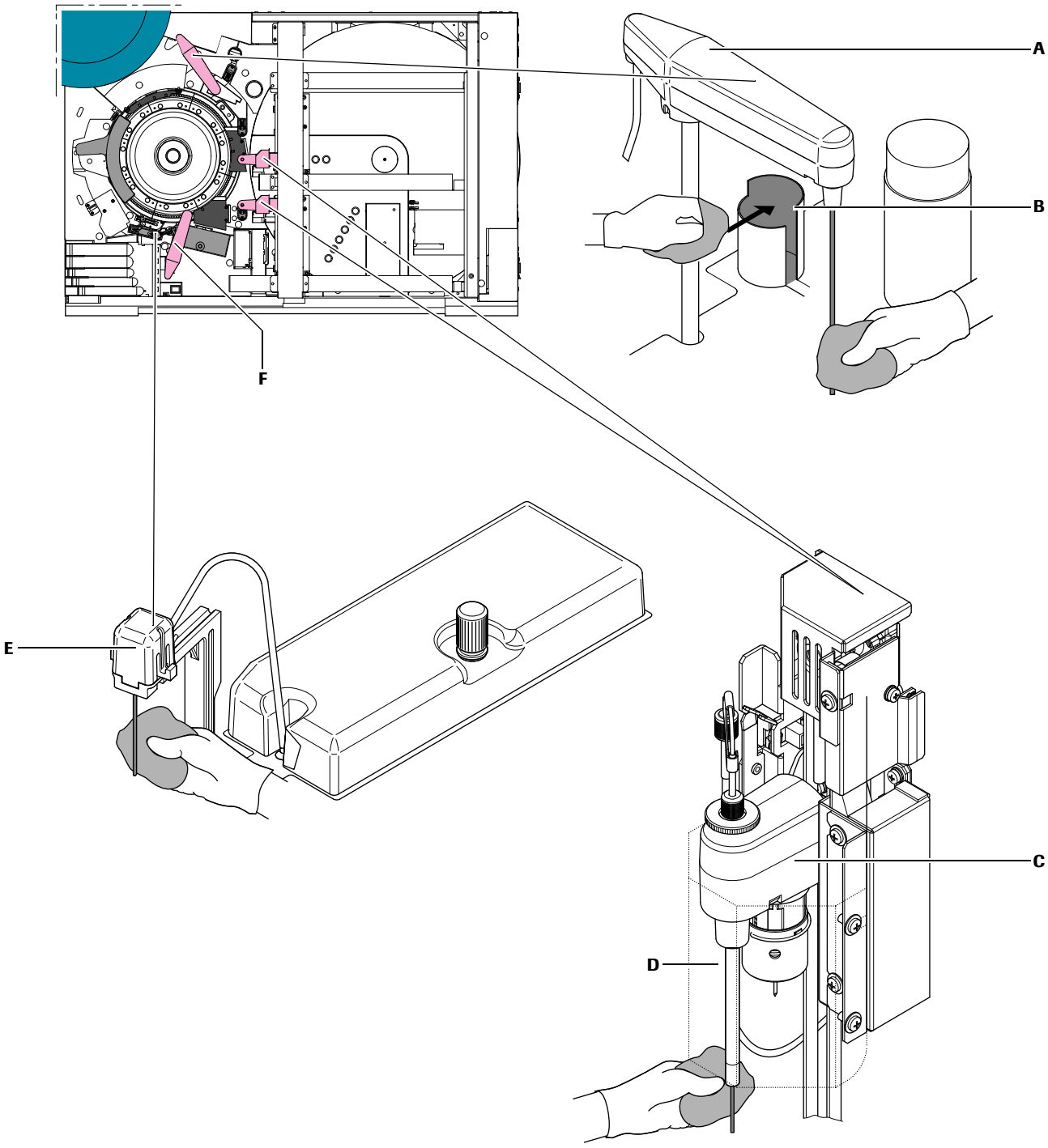
 For a description of the analyzer parts referred to in this section, see Figure C-22 on page C-74.

 The pipetter probes (**A**, **C**, **F**) and sipper nozzle (**E**) can be easily moved by hand to an accessible position.

 Use a new lint-free gauze pad for each probe to prevent cross contamination.

3. Wipe (from top to bottom) the outsides of the sample, reagent and ISE probes and the sipper nozzle with gauze pads moistened with alcohol.
4. Also wipe the inside of the shield pipe (**B**) with a gauze pad moistened with alcohol.
5. Close the top cover of the module and lock it.
6. Switch on the analyzer, if the analyzer is in shutdown status.

■



A	Sample probe	**C**	Reagent 1/2 probe	**E**	ISE sipper
B	Shield pipe	**D**	Plexiglas cover	**F**	ISE probe

Figure C-22 Cleaning the outside of sample probe with shield pipe, reagent probe, ISE probe and sipper

Cleaning cell rinse nozzles

At the end of analysis each day, clean the cell rinse nozzles. Regular cleaning prevents contamination, crystal formation, and blockages.

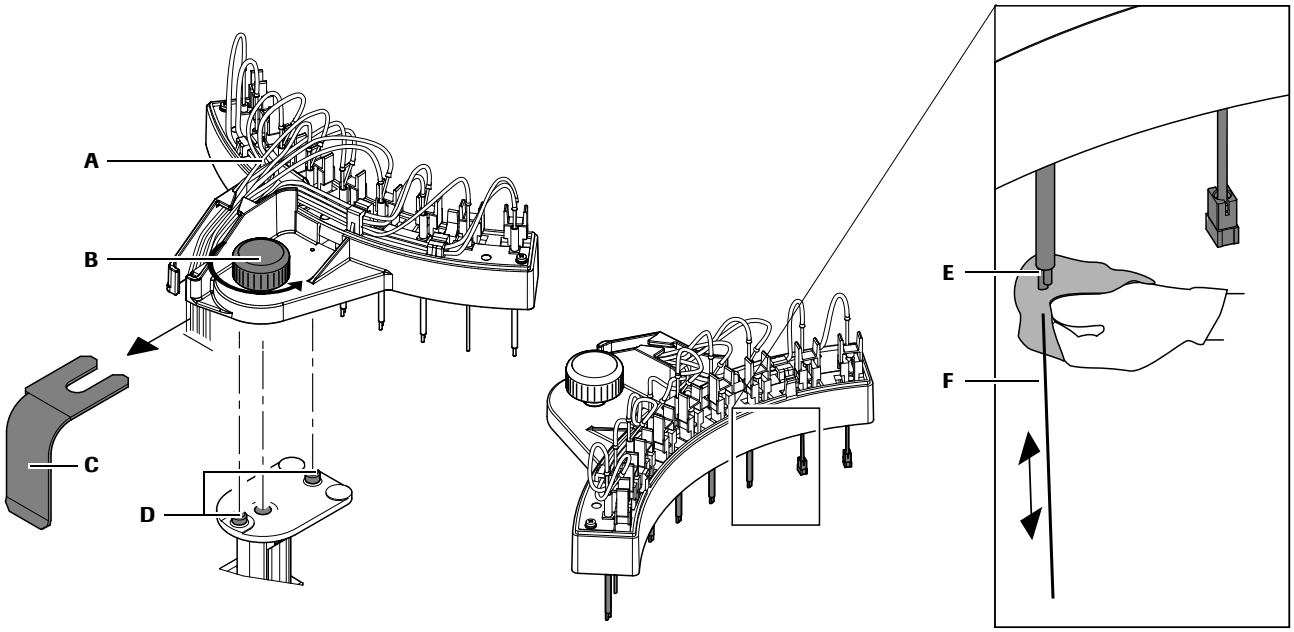
Operator time approximately 2 minutes

Materials required
- ☐ Deionized water
- ☐ Lint-free gauze pads
- ☐ Cleaning wire of 0.5 mm diameter (stainless steel)

► To clean the cell rinse nozzles

1 Put the analyzer in shutdown status or the module in standby.

2 Unlock and open the top cover of the module.



A Cell rinse unit
B Retaining screw
C Tube retainer
D Guide pins
E Nozzle tip
F Probe cleaning wire

Figure C-23 Dismount the cell rinse unit and clean the cell rinse nozzles

3 Loosen the retaining screw (**B**) of the cell rinse unit and lift off the entire unit (**A**).

4 Moisten a lint-free gauze pad with deionized water and gently wipe all tips (**E**) of the cell rinse unit nozzles in a downward motion.

5 If a nozzle is clogged, insert the probe cleaning wire (**F**) (stainless steel wire, 0.5 mm diameter) into the tip of the nozzle and eliminate the blockages.

6 Align the pin holes of the cell rinse unit with the guide pins (**D**) and attach the rinse unit.

7 Fix the tube retainer (**C**) below the screw and then tighten the retaining screw.

8 Close the top cover of the module and lock it.

9 Switch on the analyzer, if the analyzer is in shutdown status.

■

Cleaning the drain port for high concentrated waste

At the end of analysis each day, clean the outlet of the drain port for high concentrated waste. Regularly perform this maintenance to prevent the accumulation of crystals and blockages of the drain port.

Operator time approximately 1 minute

Materials required
- ☐ Cotton swabs
- ☐ Deionized water

► To clean the outlet of the drain port for high concentrated waste

1. Put the analyzer in shutdown status or the module in standby.
2. Apply deionized water to the outlet of the drain port at the rear of the module and rinse off crystals using cotton swabs.
3. Switch on the analyzer, if the analyzer is in shutdown status.

■

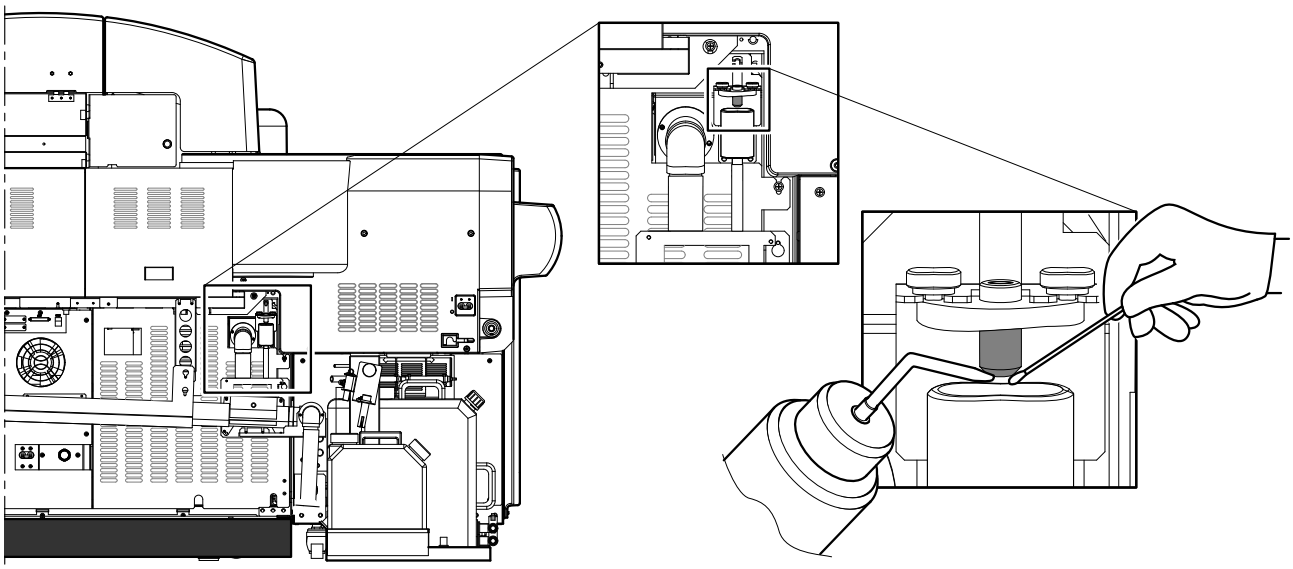


Figure C-24 Cleaning the drain port for high concentrated waste

Weekly maintenance

In this section you find all the maintenance for the **c** 501 module that must be performed at least once a week.

👁 This section discusses the following maintenance actions:
Cleaning the reaction system on page C-77
Cleaning the cell covers on page C-79
Cleaning the rinse stations on page C-81
Removing and manually cleaning the IS bath on page C-83

Cleaning the reaction system

Contamination of the reaction cells or the waste solution flow path will result in incorrect measurement results. Wash the reagent probe and reaction cells at least once a week.

👁 For instructions on how to remove reaction cells, see *Replacing reaction cells* on page C-86.

After rinsing the reaction system, perform a cell blank measurement to monitor the condition of the reaction cells.

Operator time approximately 2 minutes

System time approximately 55 minutes

This maintenance comprises the following procedures and maintenance items:

1. To rinse the reaction system (maintenance item **(7) Wash Reaction Parts**)
2. To perform a cell blank measurement (maintenance item **(4) Cell Blank Measurement**)
3. To view the cell blank measurement results

► To rinse the reaction system

1 Put the module in standby.

2 Select the **c** 501 module on the **System Overview** screen and choose **Reagent Overview**.

3 On the **Reagent** > **Status** screen, check the remaining amounts of detergents for reaction cells, reagent probe and sample probe. If inadequate, add a new detergent bottle or cassette.

Detergent	Reagent	Consumption
Sample probe detergent	Sample Cleaner 1	approximately 1 mL
Reagent probe and reaction cell detergent	NaOH-D cassettes (application code 947)	approximately 58 mL

Table C-26 Detergent consumption

4 Choose **Utility** > **Maintenance**.

5 Choose **Maintenance** (1) on the **Maintenance Types** list on the left.

6 Choose **(7) Wash Reaction Parts** on the **Maintenance** Items list on the right.

7 Choose **Select** to open the **Wash Reaction Parts** window.

8 Select a module. Selected modules are highlighted.

9 Choose **Execute**.

The procedure is finished when the module returns to standby.

Now, proceed with the cell blank measurement.

■

► To perform a cell blank measurement

1 Choose **Utility** > **Maintenance**.

2 Choose **(4) Cell Blank Measurement** on the **Maintenance** Items list on the right.

3 Choose **Select**, to open the **Cell Blank Measurement** window.

4 Select a module. Selected modules are highlighted.

5 Choose **Execute**.

■

After performing a cell blank measurement, the corresponding report can be viewed directly on the **Print View** window.

► To view the cell blank measurement results

1 Choose **Print** (global button).

2 Choose **View** to display the **Print View** window.

This window shows a short form of the **Cell Blank Measurements** report. In this short report, the cell blank values of the first cuvette are shown. This indicates that the cell blank was successful.

If an abnormal cell list is displayed below the cell blank values of the first cuvette, the cell blank failed. The cells listed did not compare to cell 1. These cells need to be inspected and the Cell Blank must be performed again.

■

Cell Blank Measurements 04/12/08 18:25

MODULE C1

ABORMAL CELL LIST

27/11/08 17:03

WAVELENGTH (nm)

CELL NO.	340	376	415	450	480	505	546	570	600	660	700	800
001	10392	9806	9625	9393	9388	9230	9065	9075	8988	8838	8716	8543
002	10422	9817	9639	9408	9403	9244	9079	9085	8997	8847	8726	8554
003	10429	9843	9660	9425	9421	9262	9099	9107	9021	8872	8749	8568
004	10522	9917	9721	9481	9472	9310	9139	9142	9053	8898	8772	8588
005	10379	9798	9612	9382	9380	9222	9060	9068	8981	8833	8711	8532
006	10421	9827	9641	9408	9404	9244	9079	9084	8998	8848	8725	8549
007	10400	9817	9628	9395	9392	9233	9068	9076	8990	8840	8719	8540
008	10503	9894	9694	9452	9440	9277	9105	9110	9020	8865	8741	8558
009	10500	9896	9692	9449	9437	9274	9102	9108	9017	8863	8737	8551
010	10509	9898	9703	9461	9452	9289	9119	9122	9033	8878	8753	8573

Figure C-25 Cell Blank Measurements report

For more information, see:
To replace reaction cells on page C-87
Cell Blank Measurements report on page E-166

Cleaning the cell covers

Clean the cell covers of the reaction cells at least once a week. The cell covers serve to prevent contamination by reagent and reaction solution. If reagent adheres to the front or rear face of a cell cover, the analytical accuracy may decrease.

Operator time approximately 5 minutes

Materials required
- ☐ Cotton swabs
- ☐ Lint-free gauze pads
- ☐ Alcohol (e.g. isopropyl alcohol or ethanol)

► To clean the cell covers

1 Put the analyzer in shutdown status or the module in standby.

2 Unlock and open the top cover of the module.

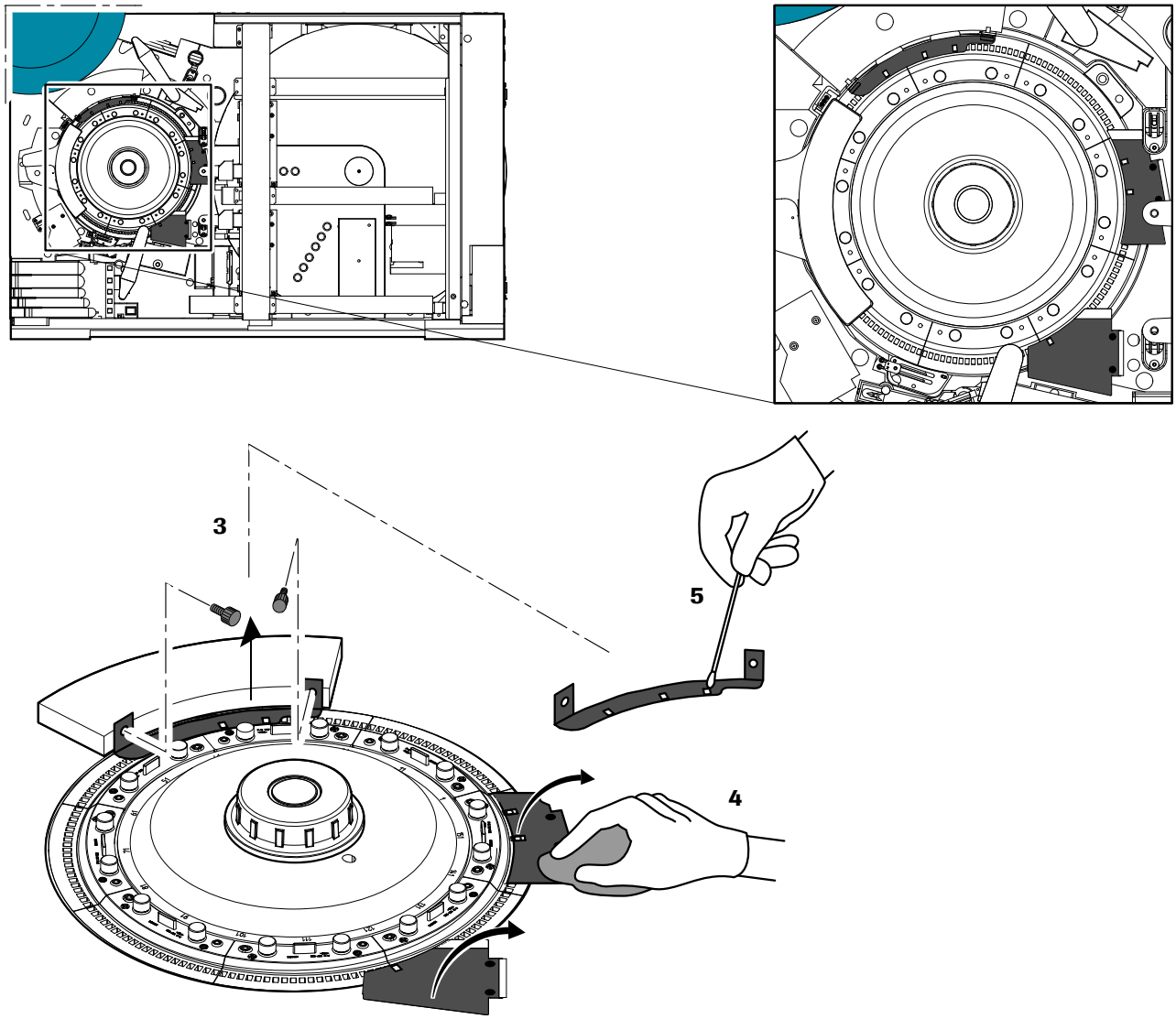


Figure C-26 Cleaning the cell covers

3 Loosen the screws and remove the cell cover above the ultrasonic mixers.

4 Wipe the front and rear faces of the cell covers using a gauze pad moistened with alcohol.

5 Wipe the openings of cell covers using a cotton swab moistened with alcohol.

Be careful not to splash alcohol in the reaction cells.

6 Return the cell cover above the ultrasonic mixers.

7 Close the top cover of the module and lock it.

8 Switch on the analyzer, if the analyzer is in shutdown status.

■

Cleaning the rinse stations

Clean the rinse stations of the sample probe, reagent probes, ISE probe and ISE sipper nozzle at least once a week, to prevent bacterial growth or precipitation that may clog the rinse stations.

Operator time approximately 5 minutes

Materials required
- ☐ Wash bottle
- ☐ Cotton swabs
- ☐ 2% EcoTergent solution
- ☐ Deionized water
- ☐ Alcohol (e.g. isopropyl alcohol or ethanol)

► To clean the rinse station

1 Put the analyzer in shutdown status or the module in standby.

2 Unlock and open the top cover of the module.

3 Move the sample probe, reagent probes, ISE probe and ISE sipper nozzle to positions that leave the rinse stations easily accessible.

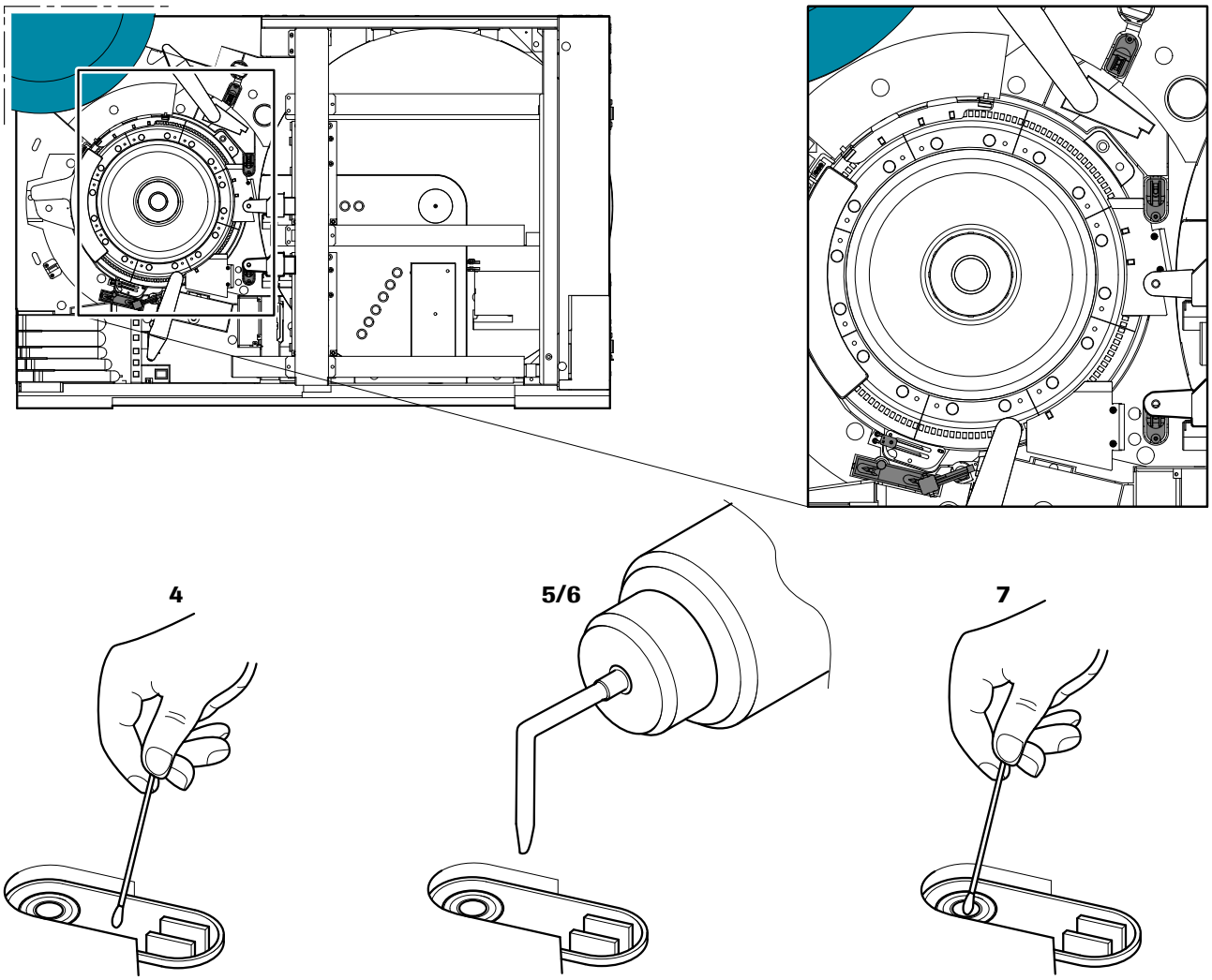


Figure C-27 Cleaning rinse stations of sample probe, reagent probe, and ISE probe

4 Using cotton swabs moistened with 2% EcoTergent solution, clean the inside of each rinse station.

5 Inject about 10 mL of 2% EcoTergent solution to each of the rinse stations.

Be careful not to splash water on the drying cylinder (for vacuum suction).

6 Inject about 100 mL of deionized water to each of the rinse stations to rinse them.

7 Wipe the drying cylinder (used for vacuum suction in the sample probe rinse station) with cotton swabs moistened with alcohol.

8 Close the top cover of the module and lock it.

9 Switch on the analyzer, if the analyzer is in shutdown status.

■

Removing and manually cleaning the IS bath

Crystals may remain on the upper part of the IS bath even after daily automatic rinsing. Therefore, remove and manually clean the IS bath once a week.

We recommend combining this maintenance with the monthly cleaning of the incubator bath. This allows the incubator bath to be cleaned below the IS bath.

See *Cleaning the incubator bath* on page C-88.

Operator time approximately 5 minutes

Materials required ☐ Deionized water

► To remove and manually clean the IS bath

1 Put the analyzer in shutdown status or the module in standby.

2 Unlock and open the top cover of analyzer.

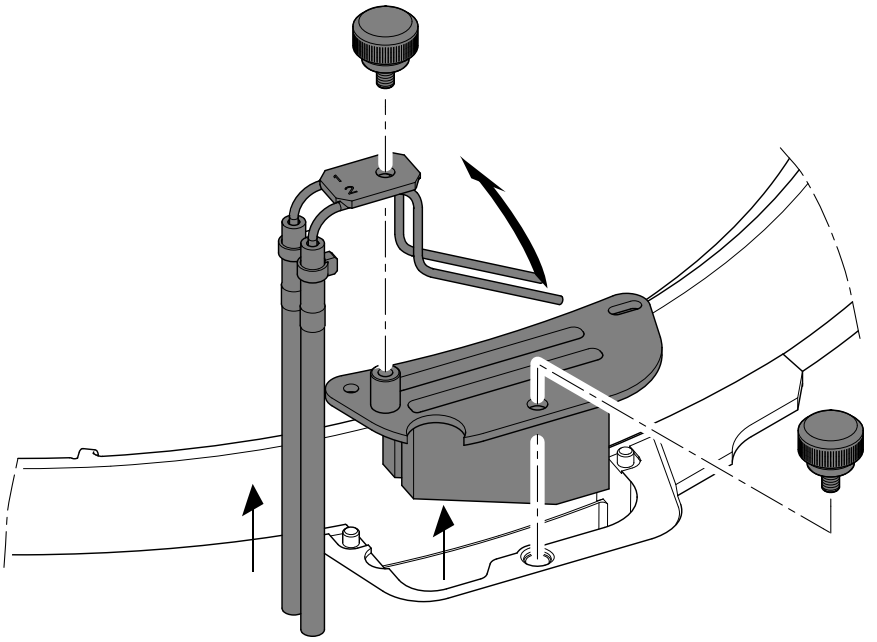


Figure C-28 Removing and cleaning the IS bath

3 Loosen the screws and remove the IS bath.

4 Wash away any crystals or contamination in the IS bath with deionized water.

5 Drain the water from the IS bath and then attach it in the analyzer.

6 Close the top cover of the module and lock it.

7 Switch on the analyzer, if the analyzer is in shutdown status.

■

Monthly maintenance

In this section, you find all the maintenance for the **c** 501 module that must be performed at least once a month.

This section discusses the following maintenance actions:
Cleaning the ISE Ref. (KCl) aspiration filter on page 84
Replacing reaction cells on page C-86
Cleaning the incubator bath on page C-88
Cleaning the detergent aspiration filters on page C-94
Cleaning the filters behind the front doors on page C-96

Cleaning the ISE Ref. (KCl) aspiration filter

Inspect the ISE Ref. aspiration filter, which is attached to the tube end in the ISE reference solution bottle. Clean the filter each time you replace the bottle but at least once a month. Blockages of the filter will reduce the accuracy of ISE Ref. aspiration and data reliability.

This maintenance comprises the following procedures and maintenance items:

1. To clean the ISE Ref. aspiration filter
2. To prime the ISE Ref. tubing

Operator time approximately 5 minutes

System time approximately 3 minutes

Materials required
- ☐ Deionized water
- ☐ Paper towel

► To clean the ISE Ref. aspiration filter

1 Put the analyzer in shutdown status or the module in standby.

2 Unlock and open the top cover of the module.

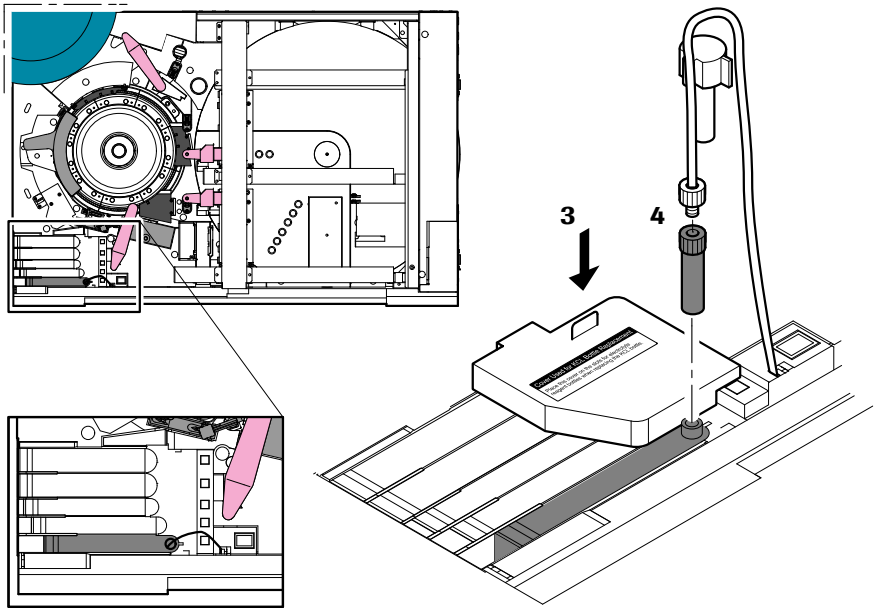


Figure C-29 Cleaning the ISE Ref. aspiration filter

CAUTION! Liquid from the tip of the tube may drop into another ISE reagent and may lead to false results. Place the dedicated cover over the ISE reagent bottles.

3 Attach the dedicated cover.

4 Remove the tubing from the ISE Ref. bottle and unscrew the filter from the tube end.

5 Clean and rinse the filter with deionized water.

6 Finally, screw the filter on the tube end and place it back into the bottle.

Make sure that the end of the tube touches the bottom of the bottle. Otherwise, reagent may not be pipetted properly.

7 Clean any spills of ISE Ref. from the surface of the instrument, using paper towels.

Damage to the ISE probe

If the dedicated cover for the ISE reagent bottles is in place during operation, the ISE pipetter probe will be damaged.

- Before starting operation, remove the dedicated cover for the ISE reagent bottles.

8 Remove the dedicated cover from the ISE reagent bottles.

9 Close the top cover of the module and lock it.

10 Switch on the analyzer, if the analyzer is in shutdown status.

After replacing the ISE Ref. aspiration filter, it is important to perform a reagent prime (maintenance item (8) Reagent Prime) for the ISE Ref. tubing.

■

► To prime the ISE Ref. tubing

1 Choose **Utility** > **Maintenance**.

2 Select **Maintenance** (1) from the **Maintenance Type** list on the left.

3 Select **(8) Reagent Prime** from the **Maintenance** Items list on the right.

4 Choose **Select** to open the **Reagent Prime** window.

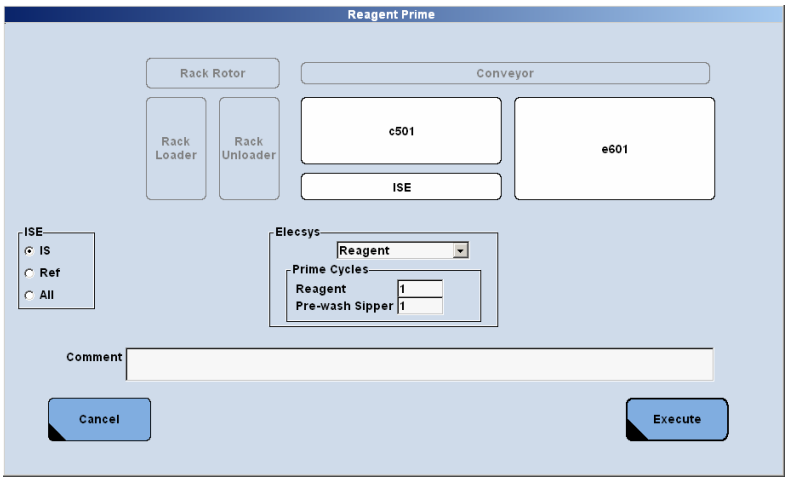


Figure C-30 Reagent Prime window

5 Select a module. Selected modules are highlighted.

6 Choose **Ref** in the **ISE** area and choose **Execute**.

The prime is complete when the system returns to standby.

■

Replacing reaction cells

Replace the reaction cells once a month because they gradually deteriorate over long use. We recommend cleaning the incubator bath and incubator bath filter at the same time.

Replacing reaction cells can be performed with the analyzer being in one of the following states:

- Shutdown status or standby (all mechanical parts can be moved by hand)
- If this maintenance is performed in combination with cleaning the incubator bath, reaction cells are replaced in incubator bath cleaning mode.

👁 *Cleaning the incubator bath* on page C-88

The decision which status or mode to choose depends on the analyzer's current status and on other maintenance actions that are to be performed.

Materials required ☐ Reaction cells

Operator time approximately 10 minutes

System time approximately 55 minutes ((7) Wash Reaction Parts, (4) Cell Blank Measurement)

► To replace reaction cells

1 Put the analyzer in shutdown status or the module in standby.

2 Unlock and open the top cover of the module.

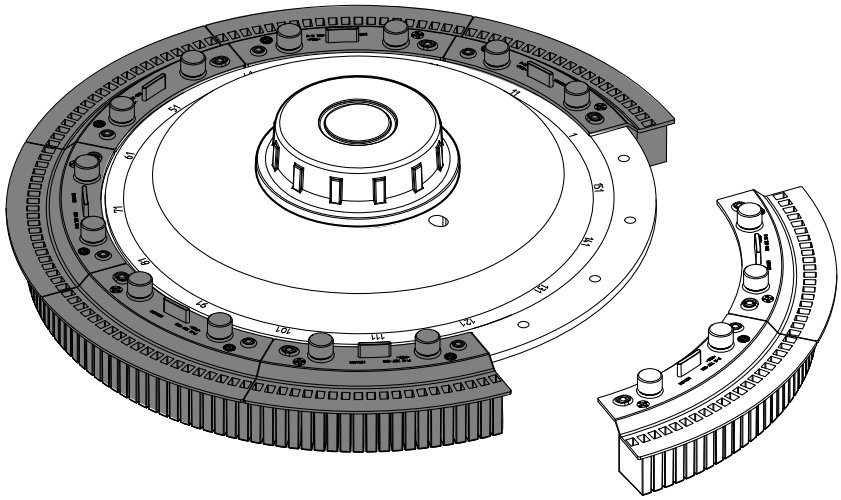


Figure C-31 Removing reaction cells

3 On each section of reaction cells, loosen and remove the thumbscrews and lift the reaction cells out of the reaction disk.

4 Discard the used reaction cells.

5 Remount new sections of reaction cells aligning them with the guide pins. Be careful not to touch the optical surfaces.

6 Switch on the analyzer, if the analyzer is in shutdown status.

After replacing reaction cells, perform the maintenance item (7) Wash Reaction Parts and then perform maintenance item (4) Cell Blank Measurement to verify the integrity of the reaction cells.

■

For detailed instructions, see:
To rinse the reaction system on page C-78
To perform a cell blank measurement on page C-78

Cleaning the incubator bath

Contamination inside the incubator bath or on the photometric window will reduce the reproducibility of measurement results. Clean the incubator bath and photometric window at least once a month.

We recommend combining this maintenance with the weekly cleaning of the IS bath, the monthly replacement of reaction cells and with the quarterly cleaning of the ultrasonic mixers.

For more information, see:
Removing and manually cleaning the IS bath on page C-83
Replacing reaction cells on page C-86
Cleaning the ultrasonic mixers on page C-98

Cleaning of the incubator bath can be performed either with the analyzer in shutdown status or with the module in incubator bath cleaning mode. These two states require different steps to be performed for this maintenance; these steps are described in two separate procedures in the remainder of this section.

For more information, see:
To clean the incubator bath (in incubator bath cleaning mode) on page C-88
To clean the incubator bath (in shutdown status) on page C-91.

Operator time approximately 15 minutes

System time approximately 25 minutes

Materials required
- ☐ Deionized water
- ☐ Cotton swabs
- ☐ Lint-free gauze pads

► To clean the incubator bath (in incubator bath cleaning mode)

1 Put the analyzer in incubator bath cleaning mode:

- Choose **Utility** > **Maintenance**.
- Select **Maintenance** (1) from the **Maintenance Type** list on the left.
- Select **(10) Incubator Bath Cleaning** from the **Maintenance** items list on the right.
- Choose **Select** to open the **Incubator Bath Cleaning** window.
- Select the appropriate module. Selected modules are highlighted.
- Choose **Execute**.

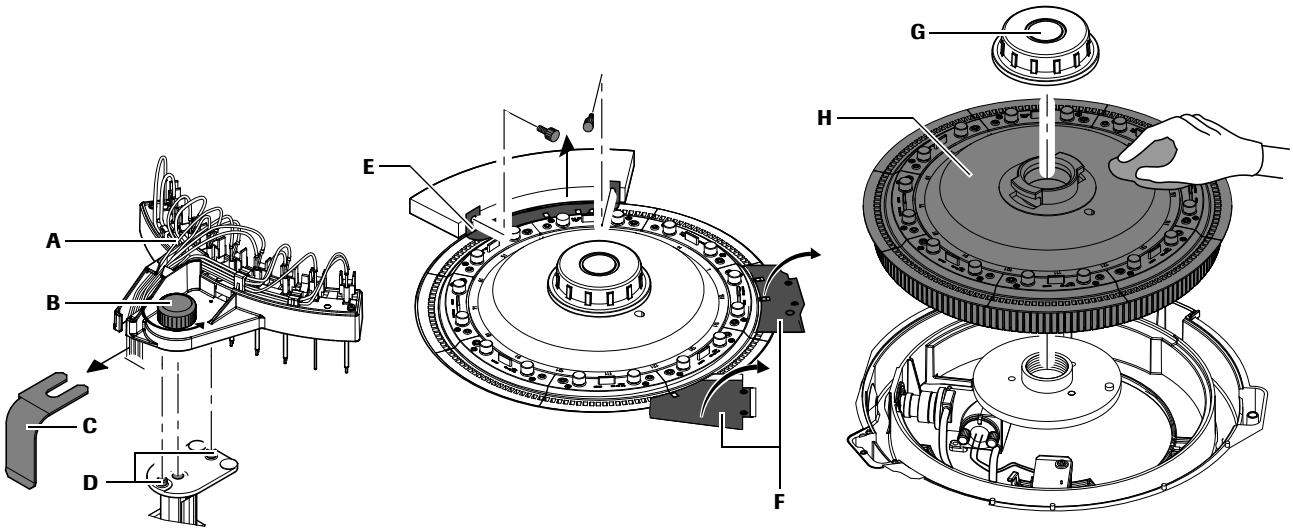
 The analyzer enters incubator bath cleaning mode and water is drained from the incubator bath.

- Choose **OK** to confirm the message of the confirmation window.
- Choose **Monitor** to open the **Maintenance Monitor** window.
- Wait until the message **Incubation Bath Cleaning (Wait Restart)** is displayed.

Do not open the top cover of the module until the corresponding message is displayed on the Maintenance Monitor.

If the top cover is opened before the message is displayed, an alarm is issued and maintenance is stopped.

2 Unlock and open the top cover of the module.



A Cell rinse unit
B Retaining screw
C Tube retainer
D Guide pins
E Cell cover of the ultrasonic mixers
F Cell covers
G Retaining nut
H Reaction disk

Figure C-32 Dismount the cell rinse unit and the reaction cells

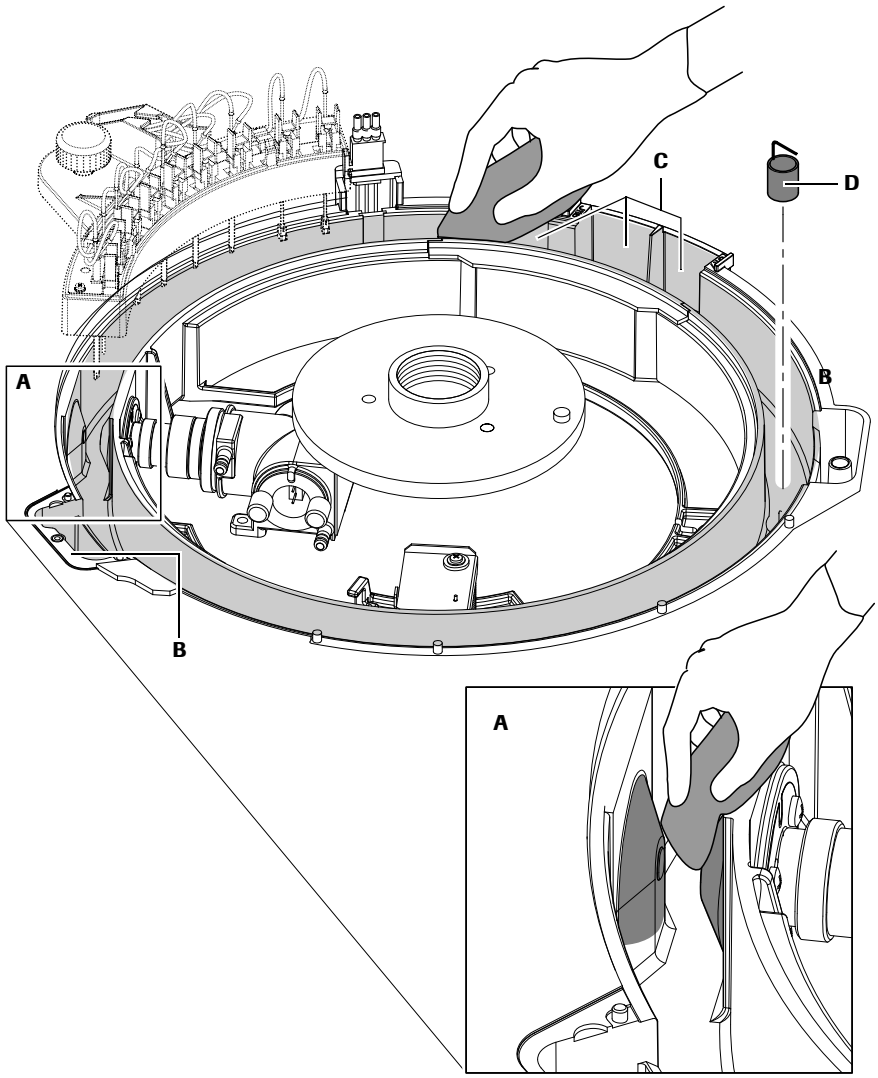
3 Loosen the retaining screw (**B**) of the cell rinse unit and lift off the entire unit (**A**).

4 Remove the cell cover above the ultrasonic mixers (**E**). Lift the cell covers (**F**) and leave them vertical.

5 Loosen the retaining nut (**G**) and remove the reaction disk (**H**) inclusive reaction cells from system. Be careful not to touch the optical surfaces.

Damage to the photometer windows

Do not scratch the photometer windows when cleaning. Use only gauze pads moistened with deionized water.



A Photometer windows
B IS bath location
C Ultrasonic mixer positions
D Drain filter

Figure C-33 Wipe the inside surfaces of the incubator bath

6 Carefully wipe the photometer windows (**A**) using a clean lint-free gauze pad moistened with deionized water.

7 If you combine this maintenance action with the weekly maintenance action *To remove and manually clean the IS bath*, remove and manually clean the IS bath.

For instructions, see *To remove and manually clean the IS bath* on page C-83.

8 Wipe the inside surfaces of the incubator bath, using a clean lint-free gauze pad. Wipe the indented part near the ultrasonic mixers (**C**) with a cotton swab.

For instructions, see *To clean the surface of the ultrasonic mixer* on page C-98.

9 Remove the incubator bath drain filter (**D**). Grasp the filter by the handle and pull up to remove.

10 Clean and rinse the filter with deionized water and return it in place.

11 If you combine this maintenance action with the maintenance action *Replacing reaction cells*, replace all sections of reaction cells against new reaction cells.

See *To replace reaction cells* on page C-87.

12 Reinstall the reaction disk (inclusive reaction cells), the cell cover of the ultrasonic mixer and the cell rinse unit.

13 Turn down the cell covers for the reagent probes.

14 Close the top cover of the module and lock it.

15 Choose Continue on the **Utility** > **Maintenance** >**Incubator Bath Cleaning** window to end the incubator bath cleaning mode.

The incubator bath is filled with water and the analyzer returns to standby.

16 Perform maintenance item (4) Cell Blank Measurement.

Perform a cell blank measurement before you resume routine operation. This is necessary to compensate for a potential change in light intensity after the cleaning of the photometric windows and replacing the reaction cells.

For instructions, see *To perform a cell blank measurement* on page C-78.

■

► To clean the incubator bath (in shutdown status)

1 Put the analyzer in shutdown status.

2 Unlock and open the top cover of the module.

3 Loosen the retaining screw of the cell rinse unit and lift off the entire unit.

4 Remove the cell cover above the ultrasonic mixers. Lift the other cell covers and leave them vertical.

Do not let all the water drain. Leave a small amount of water to just cover the bottom of the incubator bath. Close the drain by moving the tap to the Operation position.

5 Turn the tap located on the rear of the analyzer to the DRAIN position and drain the incubator bath. After draining, turn the tap back to its OPERATION position.

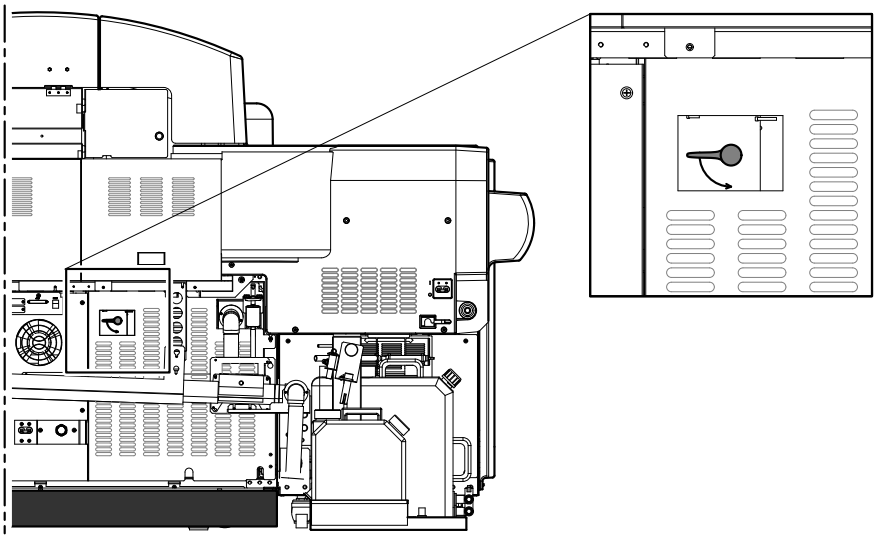
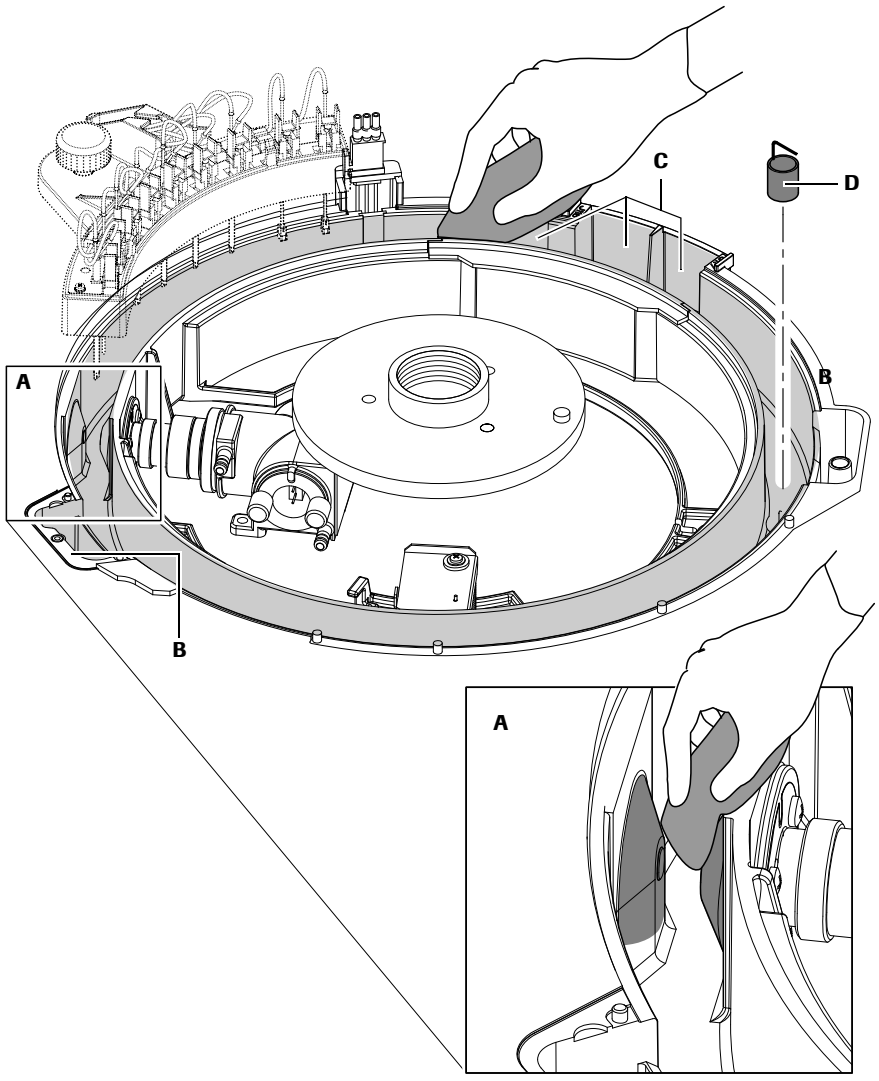


Figure C–34 Tap for manually draining the incubator bath

6 Loosen the retaining nut and remove the reaction disk inclusive reaction cells from system. Be careful not to touch the optical surfaces.

Damage to the photometer windows

Do not scratch the photometer windows when cleaning. Use only gauze pads moistened with deionized water.



A Photometer windows
B IS bath location
C Ultrasonic mixer positions
D Drain filter

Figure C-35 Wipe the inside surfaces of the incubator bath

7 Carefully wipe the photometer windows (**A**) using a clean lint-free gauze pad moistened with deionized water.

8 If you combine this maintenance action with the weekly maintenance action *To remove and manually clean the IS bath*, remove and manually clean the IS bath.

For instructions, see *To remove and manually clean the IS bath* on page C-83.

9 Wipe the inside surfaces of the incubator bath, using a clean lint-free gauze pad. Wipe the indented part near the ultrasonic mixers (**C**) with a cotton swab.

For instructions, see *To clean the surface of the ultrasonic mixer* on page C-98.

10 Remove the incubator bath drain filter (**D**). Grasp the filter by the handle and pull up to remove.

11 Clean and rinse the filter with deionized water and return it in place.

12 If you combine this maintenance action with the maintenance action *Replacing reaction cells*, replace all sections of reaction cells against new reaction cells.

See *To replace reaction cells* on page C-87.

13 Reinstall the reaction disk (inclusive reaction cells) and the cell rinse unit.

14 Reinstall the cell cover of the ultrasonic mixer and **remove one** section of reaction cells.

15 Turn down the cell covers for the reagent probes.

16 Gradually pour about 500 mL of deionized water into the incubator bath and mount the missing section of reaction cells. Be careful not to allow water to overflow from the incubator bath.

17 Close the top cover of the module and lock it.

18 Start up the analyzer.

19 Perform maintenance items (5) Incubation Water Exchange and (4) Cell Blank Measurement.

Make sure to perform a cell blank measurement before you resume routine operation. This is necessary to compensate for a potential change in light intensity after the cleaning of the photometric windows.

For instructions, see *To perform a cell blank measurement* on page C-78.

■

Cleaning the detergent aspiration filters

Inspect the detergent aspiration filters, which are attached to the tube end in the cell detergent bottles. The cell detergent bottles (Cell Wash Solution I / NaOH-D and Cell wash Solution II / Acid Wash) are located behind the left front door of the c 501 module. Clean the filter each time you replace a bottle but at least once a month. Blockages of the filter will reduce the accuracy of detergent aspiration and will lead to insufficient cell cleaning.

This maintenance comprises the following procedures and maintenance items:

1. To clean the detergent aspiration filters
2. To perform a cell detergent prime

Operator time approximately 5 minutes

System time approximately 7 minutes

Materials required
- ☐ Deionized water
- ☐ Paper towel

► To clean the detergent aspiration filters

1 Put the analyzer in shutdown status or the module in standby.

2 Open the front doors of the module and take out the detergent bottle(s).

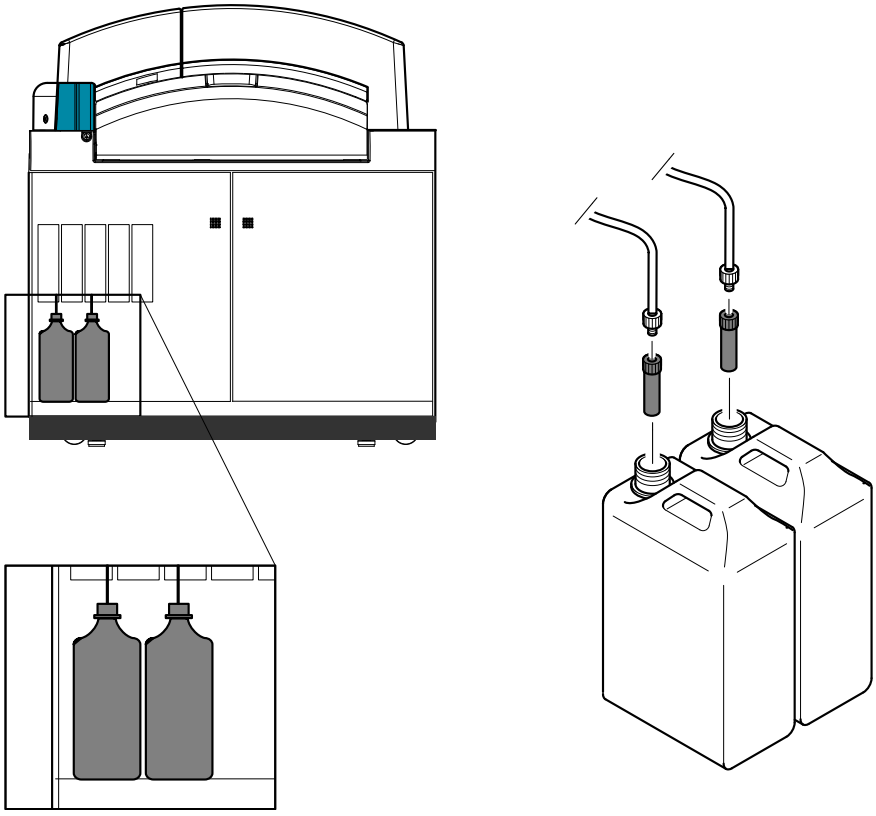


Figure C-36 Cleaning the detergent aspiration filters

3 Remove the tubing from the detergent bottle(s) and unscrew the filter from the tube end.

4 Clean and rinse the filter with deionized water.

CAUTION! Incorrect results due to incorrect insertion of aspiration tube. Insert the aspiration tube so that the end of the tube touches the bottom of the bottle. Do not bend the aspiration tube.

5 Screw the filter on the tube end and place it back into the bottle.

6 Close the front doors.

7 Switch on the analyzer, if the analyzer is in shutdown status.

8 Perform maintenance item **(9) Cell Detergent Prime**.

■

► To perform a cell detergent prime

1 Choose **Utility** > **Maintenance**.

2 Choose **(9) Cell Detergent Prime** on the **Maintenance** Items list on the right.

3 Choose **Select** to open the **Cell Detergent Prime** window.

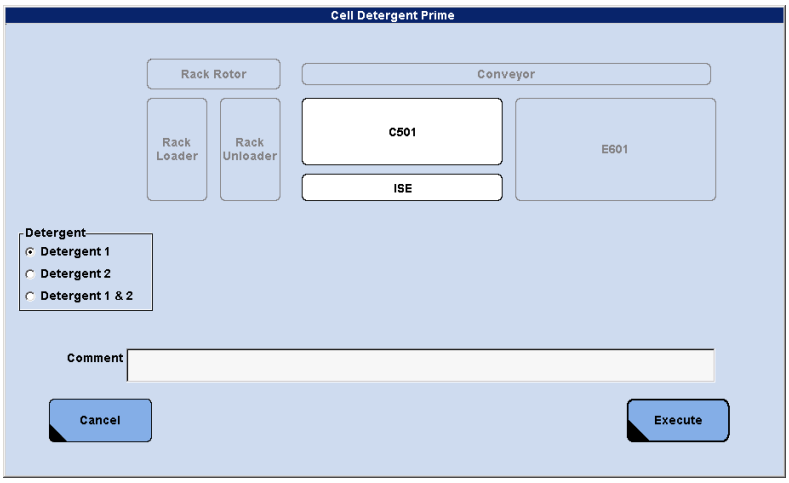


Figure C-37 Cell Detergent Prime window

4 Select a module. Selected modules are highlighted.

5 Select an option in the **Detergent** area to specify which line is to be primed.

Detergent 1 corresponds to Cell Wash Solution I / NaOH-D (basic). **Detergent 2** corresponds to Cell wash Solution II / Acid Wash (acid).

6 Choose **Execute**.

■

Cleaning the filters behind the front doors

Clean the radiator filter, the power supply filter and the filter of the circuit board rack at least once a month to prevent dust or dirt accumulation. Blockages of the filter may cause temperature rise and faulty temperature control of the analyzer.

Operator time approximately 10 minutes

Materials required
- ☐ Paper towels
- ☐ Water for rinsing
- ☐ Vacuum cleaner

⚠ CAUTION

Burns due to contact with the radiator of the refrigerator

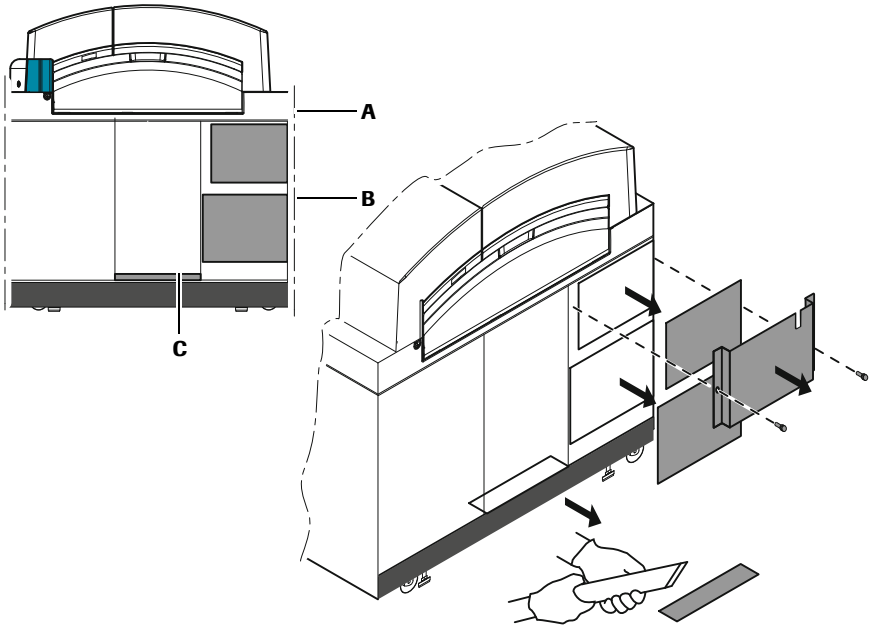
You may get burned by touching the radiator.

- Avoid touching the radiator when removing the filter.

► To clean the filters behind the front doors

1 Put the analyzer in shutdown status or the module in standby.

2 Open the front doors.



A Power supply filter
B Radiator filter
C Filter of the circuit board rack

Figure C-38 Cleaning power supply filter, the radiator filter and the filter of the circuit board rack

3 Remove the filters:

- Loosen the thumbscrews of the cover plate of the power supply filter (**A**) and remove the plate.
- Remove the power supply filter (**A**) and the radiator filter (**B**) by pulling it forward from the retaining brackets.
- Remove the filter of the circuit board rack (**C**) by pulling it out from underneath the circuit board rack.

4 Vacuum the filters. If it is conspicuously contaminated, rinse the filters with water and blot dry with paper towels.

5 Reinstall the filters:

- To reinstall the radiator filter (**B**), first insert the bottom of the filter. Then, push the top of the filter into the brackets.
- Return the power supply filter (**A**) and the filter of the circuit board rack (**C**) to their original positions.
- Return the cover plate of the power supply filter and tighten the thumbscrews.

6 Close the front doors of the module.

7 Switch on the analyzer, if the analyzer is in shutdown status.

■

Every three months maintenance

In this section, you find all the maintenance for the **c** 501 module that must be performed at least once every three months.

This section discusses the following maintenance actions:
Cleaning the ultrasonic mixers on page C-98

Cleaning the ultrasonic mixers

Clean the ultrasonic mixers every 3 months or after 225.000 tests (whatever comes first). Contamination and precipitation on the surface of the ultrasonic mixers may cause inadequate mixing and thus lead to inaccurate results.

If the ultrasonic mixer cleaning coincides with the monthly incubator bath cleaning, the procedure can be performed together.

Replacement of ultrasonic mixer

The ultrasonic output intensity is continually monitored during measurement. If the data alarm <Mix occurs frequently, replacement of the ultrasonic mixer is required. Contact your Roche service representative for the replacement.

This maintenance comprises the following procedures and maintenance items:

1. To clean the surface of the ultrasonic mixer
2. To check the intensity of the ultrasonic output

Operator time approximately 6 minutes

System time approximately 7 minutes

Materials required
- ☐ 2% EcoTergent solution
- ☐ Deionized water
- ☐ Cotton swabs

► To clean the surface of the ultrasonic mixer

1 Put the analyzer in incubator bath cleaning mode:

- Choose **Utility** > **Maintenance**.
- Select **Maintenance** (1) from the **Maintenance Type** list on the left.
- Select **(10) Incubator Bath Cleaning** from the **Maintenance** Items list on the right.
- Choose **Select** to open the **Incubator Bath Cleaning** window.
- Select the appropriate module. Selected modules are highlighted.
- Choose **Execute**.

 The analyzer turns to incubator bath cleaning mode and water is drained from the incubator bath.

- Choose **OK** to confirm the message of the confirmation window.
- Choose **Monitor** to open the **Maintenance Monitor** window.
- Wait until a message about the Incubator bath cleaning mode is displayed.

Do not open the top cover of the module until the corresponding message is displayed on the Maintenance Monitor.

If the top cover is opened before the message is displayed, an alarm is issued and maintenance is stopped.

2 Unlock and open the top cover of the module.

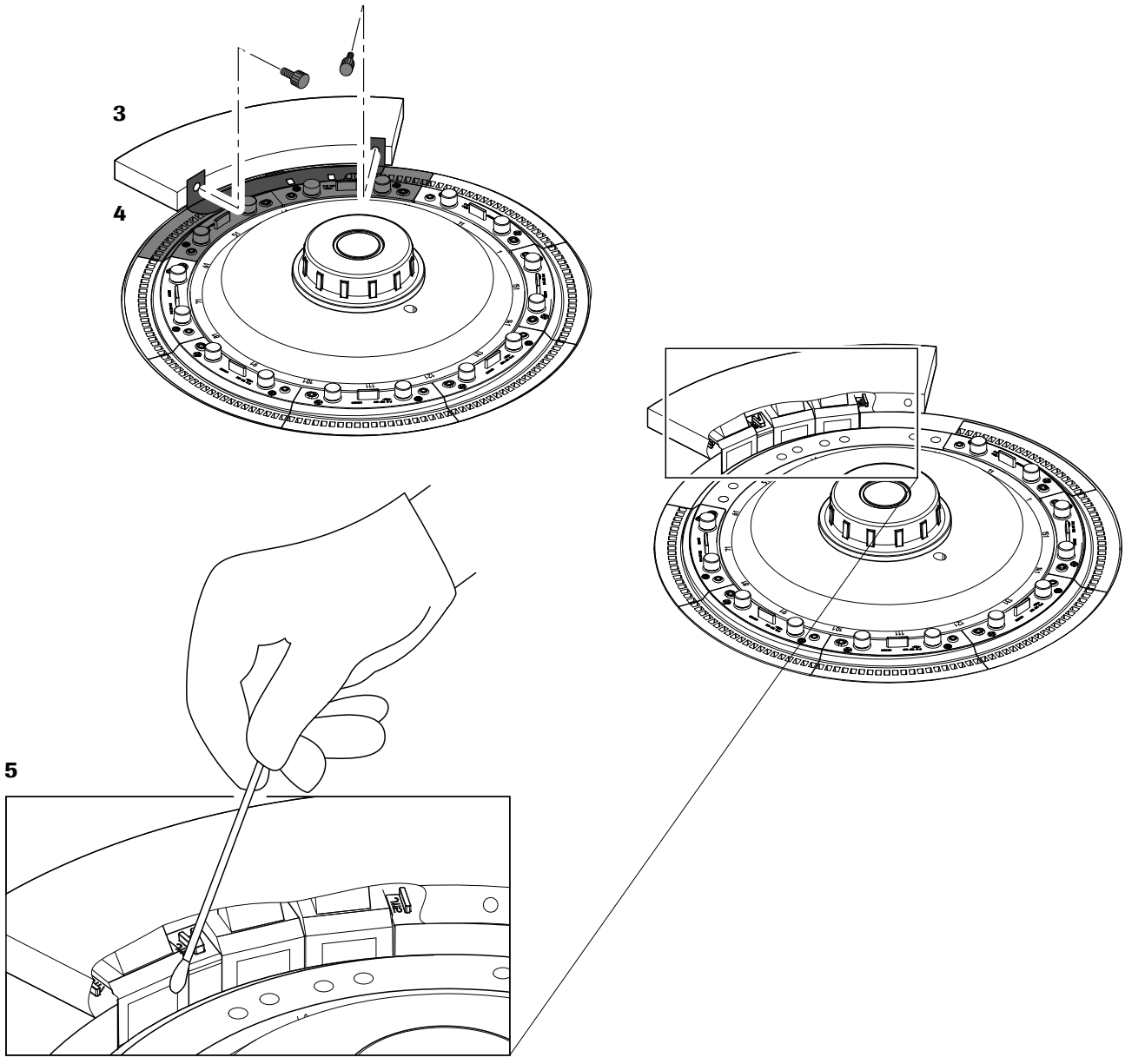


Figure C-39 Cleaning surface of ultrasonic mixer with cotton swabs

3 Remove the cell cover.

4 Loosen and remove the thumbscrews on two or three sections of reaction cells near the ultrasonic mixers. Lift the reaction cells out of the reaction disk. Be careful not to touch the optical surfaces.

5 Gently wipe the surface of the ultrasonic mixers with cotton swabs moistened with 2% EcoTergent solution. Then, wipe off the detergent with cotton swabs moistened with deionized water.

6 Return the removed sections of reaction cells.

7 Return the cell cover.

8 Close the top cover of the module and lock it.

9 Choose **Start** (global button) > **Start** to release the incubator bath cleaning mode.

Water is poured into the incubator bath.

■

► To check the intensity of the ultrasonic output

1 Choose **Utility** > **Maintenance**.

2 Select **Check (2)** from the **Maintenance Type** list on the left.

3 Select **(7) Cuvette Mixing** from the **Maintenance** Items list on the right.

4 Choose **Select**, to open the **Cuvette Mixing** window.

5 Select a module (selected modules are highlighted), and verify the **Cell Wash** check box is not selected.

Selecting the **Cell Wash** check box would rinse all reaction cells prior to the actual intensity check.

6 Choose **Execute**.

■

Every six months maintenance

In this section, you find all the maintenance for the **c** 501 module that must be performed at least once every six months.

This section discusses the following maintenance actions:
Replacing the photometer lamp on page C-101

Replacing the photometer lamp

The reproducibility of measurement will decrease if the photometer lamp deteriorates. Replace the photometer lamp if the lamp has been used for more than six months, for more than 750 hours of continuous powered-on time or if the photometer check value exceeds 14000, whatever comes first.

We recommend combining this maintenance with the monthly cleaning of incubator bath.

This maintenance comprises the following procedures and maintenance items:

1. To check the light intensity
2. To remove the photometer lamp
3. To install a new photometer lamp

Operator time approximately 5 minutes

System time approximately 20 minutes

Materials required
- ☐ Alcohol (e.g. isopropyl alcohol or ethanol)
- ☐ Lint-free gauze pads
- ☐ Photometer lamp

► To check the light intensity

1 Choose **Utility** > **Maintenance**.

2 Select **Maintenance** (1) from the **Maintenance Type** list on the left.

3 Select **(3) Photometer Check** from the **Maintenance** Items list on the right.

4 Choose **Select** to open the **Photometer Check** window.

5 Select a module. Selected modules are highlighted.

6 Select **Execute**.

Water is injected from the rinsing mechanism into reaction cell no. 1 and the absorbance of the water is measured for each available wavelength.

7 After the photometer check select **Print** (global button) to open the **Print** window.

8 Select **Print** to print a **Photometer Check** report and check the absorbance values of the current photometer check.

■

Photometer Check 8:20

PREVIOUS DATA		CURRENT DATA	
c501 DATE	05/12/1 8:20	DATE	05/12/2 8:18
340 nm	10386	340 nm	10386
376 nm	10358	376 nm	10358
415 nm	9534	415 nm	9534
450 nm	9275	450 nm	9275
480 nm	9195	480 nm	9195
505 nm	9130	505 nm	9130
546 nm	8984	546 nm	8984
570 nm	8967	570 nm	8967
600 nm	8929	600 nm	8929
660 nm	8676	660 nm	8676
700 nm	8657	700 nm	8657
800 nm	8594	800 nm	8594

Figure C-40 Photometer check report

If the current data exceed 14000, check the following points and then replace the photometer lamp:

- Verify there are no contamination or bubbles in incubator bath or photometric windows.
- Verify reaction cell no. 1 is not scratched, cracked or damaged.

If the current data value is quite different from the previous one, check for the cause!

► To remove the photometer lamp

1 Put the analyzer in shutdown status.

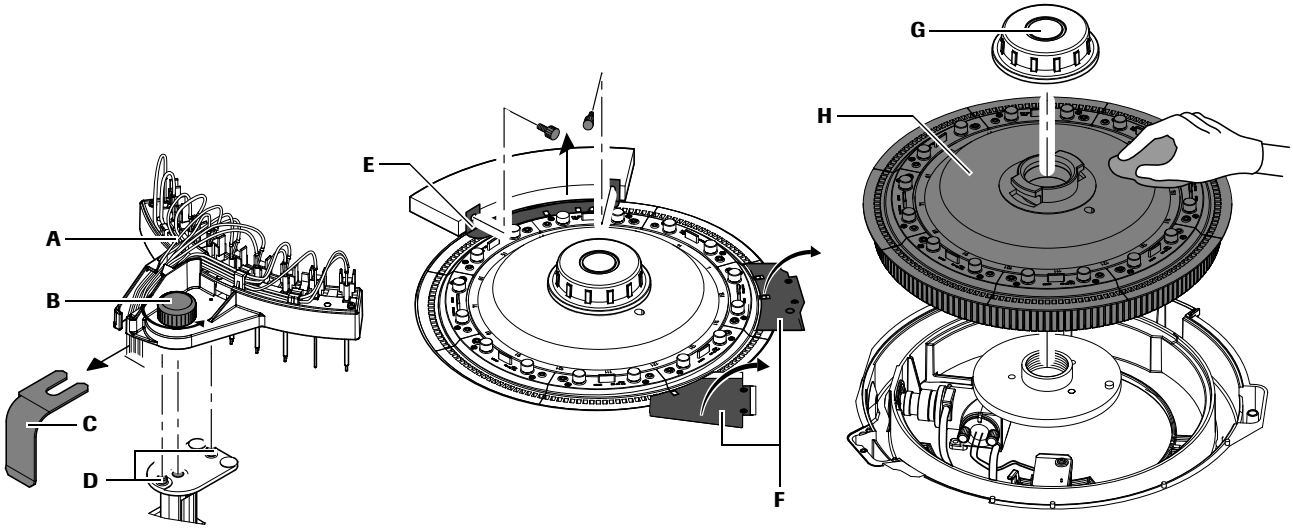
See *To shutdown the analyzer* on page C-6.

Alternatively, cut off the photometer lamp's power supply by executing the maintenance item (39) Change Light Source Lamp from the **Maintenance** Items list on **Utility** > **Maintenance**.

Alternatively, you can combine the incubator bath cleaning with the changing of the photometer lamp.

CAUTION! You may be burned if you touch any part of the photometer lamp unit. Wait about 30 minutes for the lamp and lamp housing to cool down.

2 Unlock and open the top cover of the module.



A Cell rinse unit
B Retaining screw
C Tube retainer
D Guide pins
E Cell cover of the ultrasonic mixers
F Cell covers
G Retaining nut
H Reaction disk

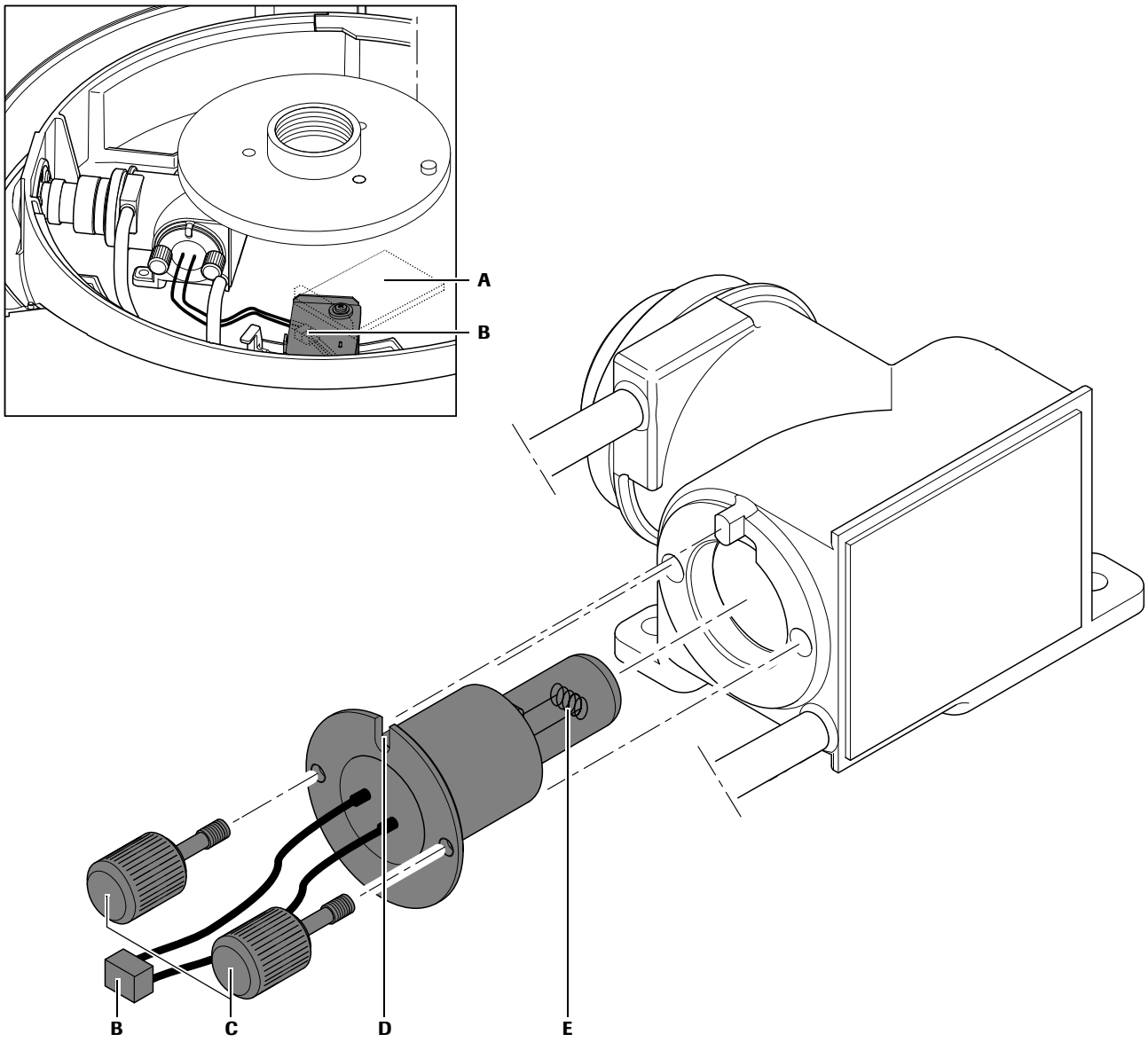
Figure C-41 Dismount the cell rinse unit and the reaction cells

3 Loosen the retaining screw (**B**) of the cell rinse unit and lift off the entire unit (**A**).

4 Remove the cell cover above the ultrasonic mixers (**E**). Lift the cell covers (**F**) and leave them vertical.

5 Loosen the retaining nut (**G**) and remove the reaction disk (**H**) inclusive reaction cells from system. Be careful not to touch the optical surfaces.

If the reaction disk is detached with the reaction cells left in place, water drops adhering to the outside of the reaction cells may drip onto the detector, causing an alarm to be issued.



A Cover of the connector
B Connector
C Retaining screws
D Pin hole of the lamp base
E Photometer lamp

Figure C-42 Replacing photometer lamp

CAUTION! You may be burned if you touch any part of the photometer lamp unit. Check that the photometer lamp unit has cooled down before replacing the lamp.

6 Rotate the connector cover (**A**) and disconnect the connector (**B**) of the lamp wire.

7 Loosen two lamp retaining screws (**C**) and pull out the photometer lamp (**E**).

When the screws become easy to turn, the lamp can be detached.

8 Carefully remove the retaining screws from the lamp base. These are needed to install the new lamp.

■

► To install a new photometer lamp

1 Insert the retaining screws in the new lamp.

2 Insert the new photometer lamp:

- Align the pin hole (**D**) in the lamp base with the guide pin of the lamp housing
- Tighten the two lamp retaining screws (**C**).



If you have touched the glass part of the new photometer lamp, wipe it off with a gauze pad moistened with alcohol.

3 Connect the connectors of the lamp wires.

Do not let the lamp wires float up from the unit.

4 Reinstall the reaction disk with the reaction cells and close the cell covers.

5 Mount the cell rinse unit to its original position.

6 Close the top cover of the module and lock it.

7 Start up the analyzer again or—if maintenance item (39) Change Light Source Lamp has been executed without shutting down the analyzer—choose **Cancel Maintenance** on the **System Overview** screen.

8 Wait about 30 minutes for the photometer lamp to stabilize.

Finally, perform a cell blank measurement before you resume routine operation. This is necessary to compensate for a potential change in light intensity.

For instructions, see *To perform a cell blank measurement* on page C-78.

■

As needed maintenance

In this section, you find all the maintenance for **c** 501 module that must be performed as needed and are not subject to a regular time schedule.

👁 This section discusses the following maintenance actions:
Replacing nozzle tips on cell rinse nozzles on page C-106
Draining the vacuum tank on page C-109

Cleaning the ISE Ref. (KCl) aspiration filter

Inspect the ISE Ref. aspiration filter, which is attached to the tube end in the ISE reference solution bottle. Clean the filter each time you replace the bottle but at least once a month. Blockages of the filter will reduce the accuracy of ISE Ref. aspiration and data reliability.

👁 See *Cleaning the ISE Ref. (KCl) aspiration filter* on page C-84.

Cleaning the detergent aspiration filters

Inspect the detergent aspiration filters, which are attached to the tube end in the cell detergent bottles. The cell detergent bottles (Cell Wash Solution I / NaOH-D and Cell wash Solution II / Acid Wash) are located behind the left front door of the c 501 module. Clean the filter each time you replace a bottle but at least once a month. Blockages of the filter will reduce the accuracy of detergent aspiration and will lead to insufficient cell cleaning.

👁 See *Cleaning the detergent aspiration filters* on page C-106.

Replacing nozzle tips on cell rinse nozzles

Replace the nozzle tips on the cell rinse nozzles if they are worn but latest after 225.000 tests. The replacement cycle is typically one to two years depending on conditions of use.

Replace a nozzle tip if its corner or bottom is worn so that water remains in the reaction cell.

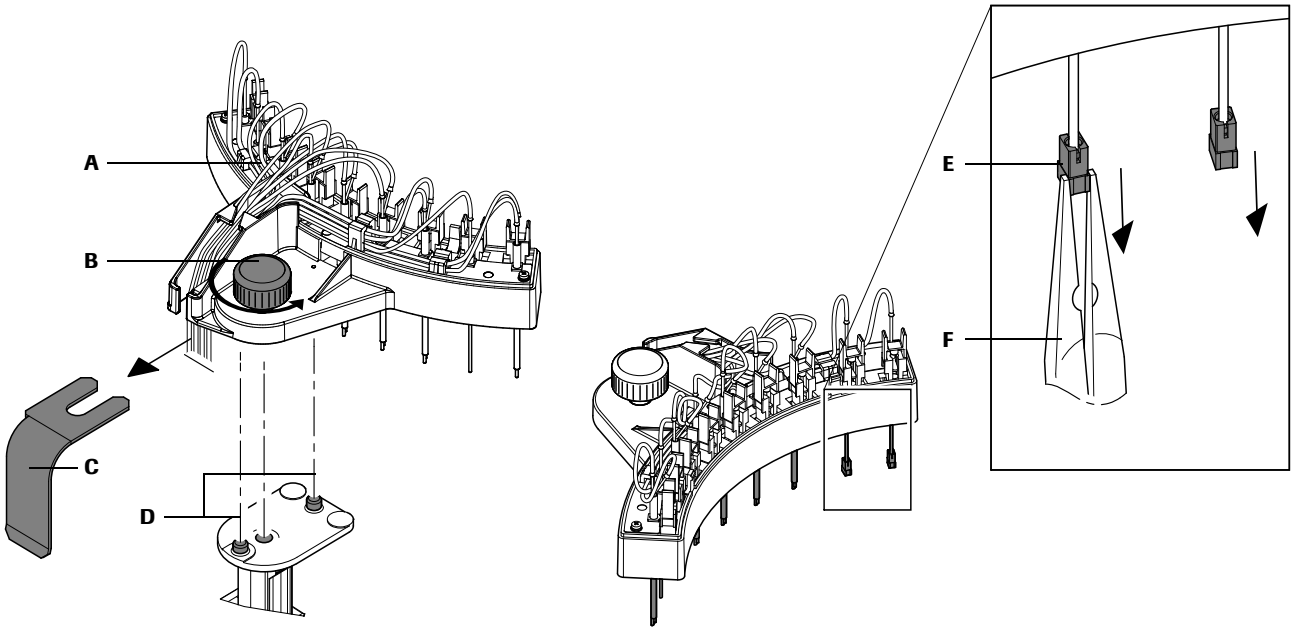
Operator time approximately 6 minutes

Materials required
- ☐ Needle-nose pliers
- ☐ Nozzle tip

► To replace the cell rinse nozzle tips

1 Put the analyzer in shutdown status or the module in standby.

2 Unlock and open the top cover of the module.

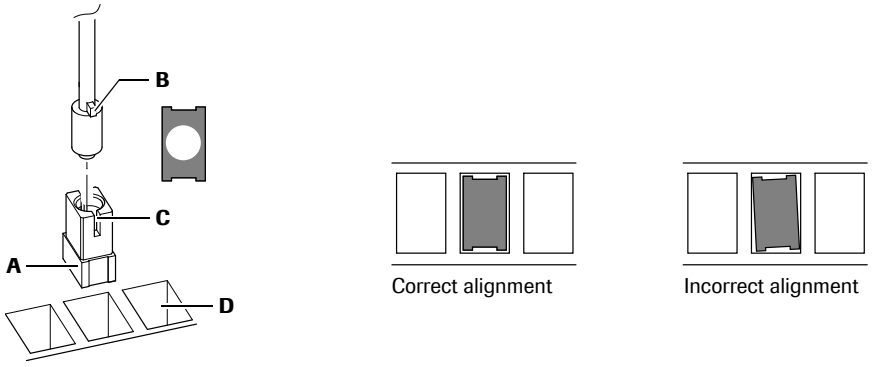


A Cell rinse unit
B Retaining screw
C Tube retainer
D Guide pins
E Nozzle tip
F Needle-nose pliers

Figure C-43 Dismount the cell rinse unit and replace the nozzle tips

3 Loosen the retaining screw (**B**) of the cell rinse unit and lift off the entire unit (**A**).

4 Grasp the sides of the nozzle tip (**E**) with needle-nose pliers (**F**) and pull it out.



A Nozzle tip
B Guide pin
C Guide groove
D Reaction cell

Figure C-44 Alignment of a nozzle tip in relation to reaction cells

5 Insert a new nozzle tip (**A**) by hand aligning it with the guides (**B**, **C**).

6 Align the pin holes of the cell rinse unit with the guide pins (**D**, Figure C-43) and attach the rinse unit.

7 Fix the tube retainer (**C**, Figure C-43) below the screw and then mount the unit.

8 Make sure the nozzle tip is not at a slant relative to the reaction cell.

9 Close the top cover of the module and lock it.

10 Switch on the analyzer, if the analyzer is in shutdown status.

■

Cleaning the ultrasonic mixers

Clean the ultrasonic mixers every 3 months or after 225.000 tests (whatever comes first). Contamination and precipitation on the surface of the ultrasonic mixers may cause inadequate mixing and thus lead to inaccurate results.

See *Cleaning the ultrasonic mixers* on page C-98.

Replacing the photometer lamp

The reproducibility of measurement will decrease if the photometer lamp deteriorates. Replace the photometer lamp if the lamp has been used for more than six months, for more than 750 hours of continuous powered-on time or if the photometer check value exceeds 14000, whatever comes first.

See *Replacing the photometer lamp* on page C-101.

Draining the vacuum tank

An alarm is issued (Liquid in vacuum tank) when there is water or waste solution in the vacuum tank. If this alarm appears, the vacuum tank must be drained. In case this happens frequently, contact the Roche service representative.

Operator time approximately 5 minutes

Materials required ☐ Beaker

► To drain the vacuum tank

1 Shut down the analyzer or power off the **c** 501 module.

2 Open the front doors of the **c** 501 and locate the vacuum tank.

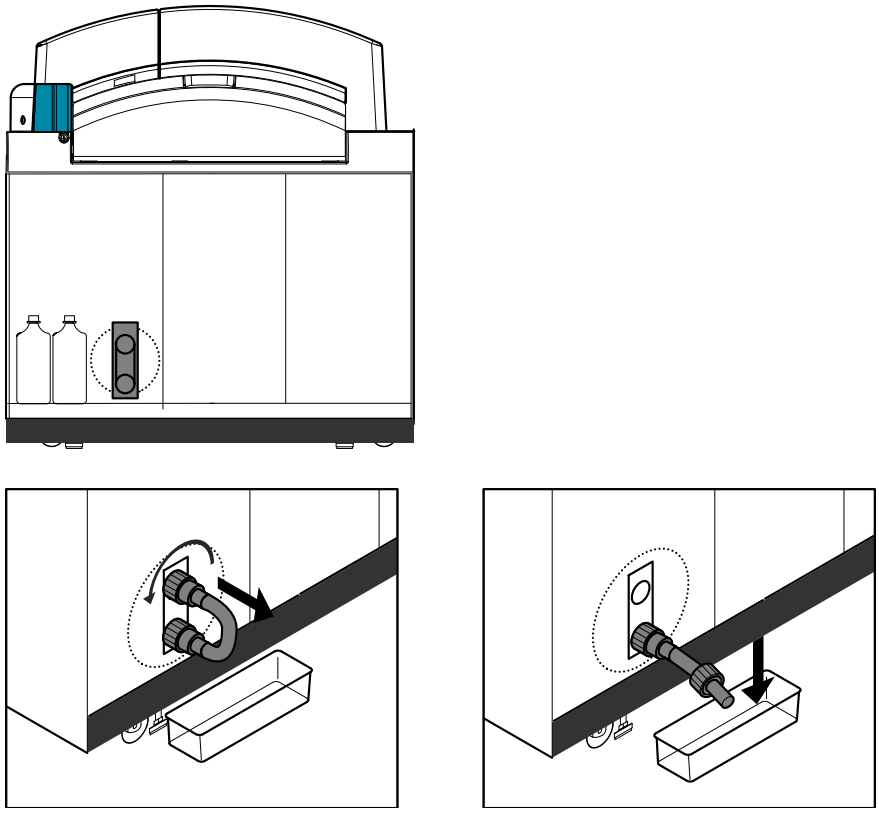


Figure C-45 Draining the vacuum tank

3 Remove the cap holding the drain tube of the vacuum tank.

4 Drain the waste solution into a beaker.

5 Replace the drain tube and reattach the cap to secure the drain tube.

6 Close the front doors of the module.

7 Switch on the analyzer, if the analyzer is in shutdown status.

■

Cleaning instrument surfaces

Spills on the instrument surface could be potentially biohazardous and damage the surface.

Operator time approximately 5 minutes

Materials required
- ☐ Cloth or paper towels
- ☐ Laboratory disinfectant (no alcohol or bleach)

► To clean instrument surfaces

1 Put the analyzer in shutdown status or the module in standby.

2 Unlock and open the top cover of the module.

3 Clean the module surfaces using a cloth or paper towel moistened with disinfectant.

Clean up all spills immediately. Use this procedure to ensure that surfaces are clean. If necessary, move the probes or units manually to clean the surface.

4 Close the top cover and lock it with the key.

■

Extended Power OFF procedures

If the system is not used for an extended period of time, it is important to ensure that the system is properly prepared and that the correct shut down maintenance has been performed.

Time period (Days)	Power OFF procedure	Power ON procedure
1 to 2	Power OFF 1	Power ON 1
3 to 7	Power OFF 2	Power ON 2
8 or more	When the instrument was not in use for a period longer than 8 days, call Roche service representative. The necessary procedure is performed by your Roche service representative.	

Table C-27 Extended power OFF procedures

Power OFF 1

Use this procedure if the instrument will not be in use for 1 to 2 days (e.g., a weekend).

► Power OFF 1

1. Choose **Shut Down** (global button) to display the **Shut Down** window.
2. Select the **Shut Down** option and choose **Execute** to confirm the shutdown.
3. Wait until the computer power supply turns off. Then, switch off the power switch of the printer and monitor.

 CAUTION! Damage to the control unit or data loss. Before switching-off of the analyzer, make sure the monitor indication has changed from shutdown to a state where nothing is displayed.
4. Switch off the operation power switch on the left side face of the rack sampler unit.
5. Turn off the water supply.
6. Remove and cap the ISE IS and ISE Dil. bottles.

 Store the ISE IS and ISE Dil. bottles at room temperature.
7. Close the top cover.

■

Power OFF 2

Use the following procedure if the instrument will not be used for 3 to 7 days.

► Power OFF 2

1 Choose **Shut Down** (global button) to display the **Shut Down** window.

2 Select the **Shut Down** option and choose **Execute** to confirm the shutdown.

3 Wait until the computer power supply turns off. Then, switch off the power switch of the printer and monitor.

CAUTION! Damage to the control unit or data loss. Before switching-off of the analyzer, make sure the monitor indication has changed from shutdown to a state where nothing is displayed.

4 Switch off the operation power switch on the left side face of the rack sampler unit.

5 Turn off the water supply.

6 Remove and cap the ISE IS and ISE Dil. bottles.

Store the ISE IS and ISE Dil. bottles at room temperature.

7 Remove the reaction cells.

Store the reaction cells in deionized water. All reaction cells must be filled with deionized water.

8 Close the top cover.

■

Power ON procedures (after Extended Power OFF)

Power ON 1 The procedure below correspons to *Power OFF 1*, an extended Power OFF procedure applied if the instrument will not be in use for 1 to 2 days (for example, a weekend).

► To start the system

1 Switch on the water supply of the system.

2 Place ISE IS and ISE Dil. bottles into the reagent position and uncap them.

3 Switch on the operation power switch, located on the left side of the rack sampler unit.

The analyzer starts the initialization routine (time for **c** 501, **e** 601, and control unit approximately 12 min).

4 Switch on each power switch of the computer, printer, and monitor. While the analyzer is performing initialization the **Logon** screen is displayed.

5 Enter your Operator ID and password to log on.

6 Choose **OK** to gain access to the software. When initialization is completed, the analyzer goes into standby.

7 Perform the *Power ON* maintenance pipe.

👁 See:
Performing maintenance items or pipes on page C-13
Power ON on page C-32

■

Power ON 2 The procedure below correspons to *Power OFF 2*, an extended Power OFF procedure applied if the instrument will not be used for 3 to 7 days.

► To start the system

1. Switch on the water supply of the system.
2. Check the water level of the incubator bath.

 If necessary, refill with deionized water.
3. Place reaction cells on the reaction disk.
4. Place ISE IS and ISE Dil. bottles into the reagent position and uncap them.
5. Switch on the operation power switch, located on the left side of the rack sampler unit.

 The analyzer starts the initialization routine (time for **c** 501, **e** 601, and control unit approximately 12 min).
6. Switch on each power switch of the computer, printer, and monitor. While the analyzer is performing initialization the **Logon** screen is displayed.
7. Enter your Operator ID and password to log on.
8. Choose **OK** to gain access to the software and begin operation. When initialization is completed, the analyzer goes into standby.
9. Perform the *Power ON* and the *Weekly* maintenance pipe.

 👁 See:
 Performing maintenance items or pipes on page C-13
 Power ON on page C-32
 Weekly shutdown on page C-33

■

Maintenance e 601

This chapter describes the maintenance actions required for correct and efficient running of the **e** 601 module. The required schedule of the maintenance actions, for example, daily, weekly, and quarterly is provided as well as actions that are performed as needed.

In this chapter *Chapter* 18

Maintenance schedule C-117
Daily maintenance C-118
Cleaning probes and sippers C-118
Weekly maintenance C-121
Cleaning ProCell/CleanCell nozzles and replace reservoirs C-121
Cleaning mixing station and separation stations of the Pre-wash area C-125
Cleaning incubator C-128
Cleaning vortex mixing station C-130
Cleaning microbead mixer C-132
Cleaning rinse stations C-134
Every two weeks maintenance C-137
Liquid flow path cleaning C-137
Every three months maintenance C-140
Replacing e 601 pinch valve tubing C-140
As needed C-143
Cleaning ProCell/CleanCell stand and aspiration tubes C-143
Cleaning reagent disk and compartment C-146
Cleaning solid waste compartment C-148
Cleaning instrument surfaces C-150
Finalization C-151
Extended Power OFF procedures C-152
Power OFF 1 C-152
Power OFF 2 C-153
Power ON procedures (after Extended Power OFF) C-156

Maintenance schedule

All maintenance actions are listed in descending frequency.

PO	Power OFF
SB	Stand by
MM	Module Masked
MC	Manual Cleaning

Procedure		Mode	Operator Time (min)	System Time (min)	Page
Daily	Cleaning probes and sippers	MC	5		C-118
Weekly	Cleaning ProCell/CleanCell nozzles and replace reservoirs	MC	8	15	C-121
	Cleaning mixing station and separation stations of the Pre-wash area	MC	5		C-125
	Cleaning incubator	MM	10		C-128
	Cleaning vortex mixing station	MC	2		C-130
	Cleaning microbead mixer	MC	2		C-132
	Cleaning rinse stations	MC	5		C-134
Every 2 weeks	Liquid flow path cleaning	SB	5	30	C-137
Every 3 month	Replacing e 601 pinch valve tubing	SB/PO	5	30	C-140
As Needed	Cleaning ProCell/CleanCell stand and aspiration tubes	SB	5	15	C-143
	Cleaning reagent disk and compartment	MM	10		C-146
	Cleaning solid waste compartment	MM	5		C-148
	Cleaning instrument surfaces	MM	5		C-150
	Finalization	SB			C-151
	Extended Power OFF procedures	SB			C-152

Table C-28 Maintenance schedule

Daily maintenance

In this section you find all the maintenance for the **e** 601 module that must be performed every day.

Cleaning probes and sippers

Clean the reagent probe, sample probe, sipper probes and Pre-wash sippers to remove residual solution and precipitation. Impurities on the sample probe may cause problems and affect results. After cleaning the probe, its discharge and operation should be checked. When cleaning, take care not to bend or damage the probes or sippers.

Operator time approximately 5 minutes

Materials required
- ☐ Lint-free gauze squares
- ☐ Alcohol (e.g. isopropyl alcohol or ethanol)
- ☐ Deionized water
- ☐ Paper towel

Damage to the probes

- Do not bend or damage the lower end of the probes during cleaning. Move the arm gently. Do not move it up and down.
- Use new lint-free gauze square for each probe to prevent cross contamination.
- Do not bend the electrode for LLD inside the reservoir. If they are bent, contact the Roche service representative.

► To position probes for maintenance

1. Choose **Utility** > **Maintenance**.
2. Choose **Maintenance** on the **Maintenance Type** list.
3. Choose **(29) Manual Cleaning** on the **Maintenance** Items list.
4. Choose **Select** to display the **Manual Cleaning** window.
5. Select the appropriate **e** 601 module and deselect all other modules and units. Selected modules are highlighted in white.
6. Choose **Execute**. The probes on the selected module(s) move to their cleaning positions. After all movement has stopped, manual cleaning can begin.

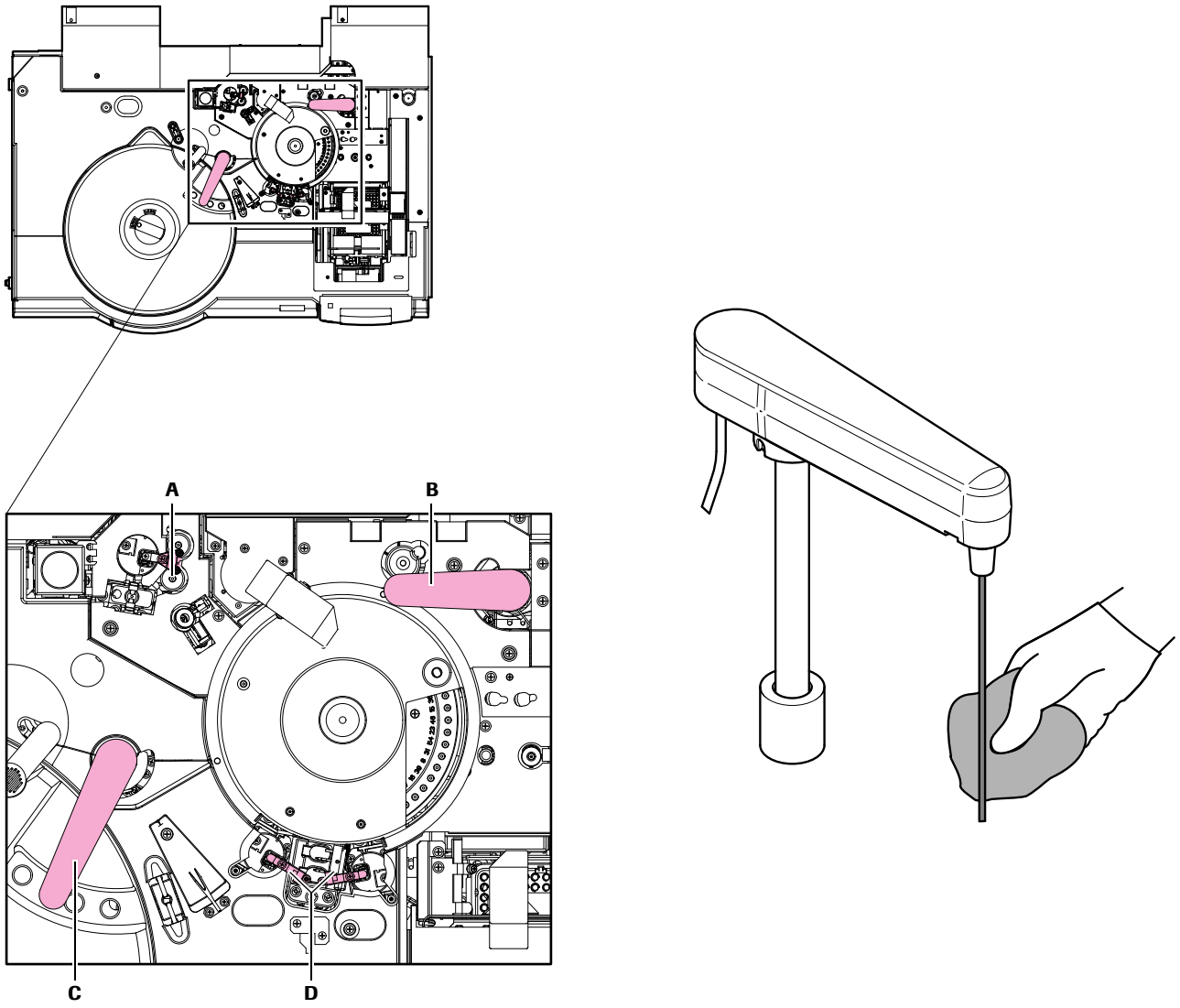
■

► To clean probes

1 Touch a screw on the rack sampler unit in order to ground any static charge which may have built-up on you.

2 Open the top cover.

3 To ensure no alcohol drops into the module, place a paper towel underneath the probe.



A Pre-wash probes (sipper, dispenser) **C** Reagent probe

B Sample probe **D** Sipper probes for measuring cells 1 and 2

Figure C-46 Cleaning probes and sippers

4 Clean the probes and sippers using the following procedures.

- Sample probe

 Wipe the probe from top to bottom in a downward motion with lint-free gauze square soaked in deionized water.

 If the probe still appears dirty, wipe the outer surface with lint-free gauze square soaked in alcohol, then immediately with deionized water.

- Reagent probe
- Sipper probes for measuring cells 1 and 2
- Pre-wash sipper and dispenser probe

 Wipe each of the probes from top to bottom in a downward motion with lint-free gauze square soaked in alcohol, followed by lint-free gauze square moistened with deionized water.

5 Remove the paper towels from the module.

6 Close top cover and lock it with the key.

7 Choose **Stop** (global button) once cleaning has been completed.

8 Choose **Yes** to stop maintenance after confirmation.

■

► To return probes to standby positions

1 Choose **Utility** > **Maintenance**.

2 Select **Maintenance** on the **Maintenance Type** list.

3 Select **(1) Reset** on the **Maintenance** Items list.

4 Choose **Select** to display the **Reset** window.

5 Select the appropriate **e** 601 module and deselect all other modules and units. Selected modules are highlighted in white.

6 Choose **Execute**. The probes on the selected module(s) return to their standby positions.

■

Weekly maintenance

In this section you find all the maintenance for the **e** 601 module that must be performed at least once a week.

Cleaning ProCell/CleanCell nozzles and replace reservoirs

As ProCell dries, crystals are formed. To prevent problems, the ProCell/CleanCell filling nozzles and electrodes must be cleaned and the reservoirs must be replaced regularly.

This maintenance is divided into 5 procedures and must be performed in the order specified:

- Procedure 1 – To empty ProCell/CleanCell reservoirs
- Procedure 2 – To clean nozzles and electrodes
- Procedure 3 – To replace ProCell/CleanCell reservoirs
- Procedure 4 – To perform Reagent Prime
- Procedure 5 – To perform Finalization

Operator time approximately 8 minutes

System time approximately 15 minutes

Materials required
- ☐ Cotton tipped applicator sticks
- ☐ Deionized water
- ☐ 2 ProCell/CleanCell reservoirs

► Procedure 1 – To empty ProCell/CleanCell reservoirs

1. Choose **Utility** > **Maintenance**.
2. Select **Maintenance** from the **Maintenance Type** list.
3. Select **(33) Empty PC/CC Reservoir** from the **Maintenance** Items list.
4. Choose **Select** to display the **Empty PC/CC Reservoir** window.
5. Select the appropriate **e** 601 module and deselect all other modules and units. Selected modules are highlighted in white.
6. Choose **Execute**. The PC/CC reservoirs are emptied.
7. After the procedure has been completed, the **e** 601 module goes into standby mode.

■

► Procedure 2 – To clean nozzles and electrodes

1 Make sure that the module is in standby.

2 Touch a screw on the rack sampler unit in order to ground any static charge which may have built-up on you.

3 Open the top cover.

Damage to the sipper probes

- Do not bend or damage the lower end of the sipper probes during cleaning. Move the arm gently. Do not move it up and down.
- Do not bend the electrode for LLD inside the reservoir. If they are bent, contact the Roche service representative.

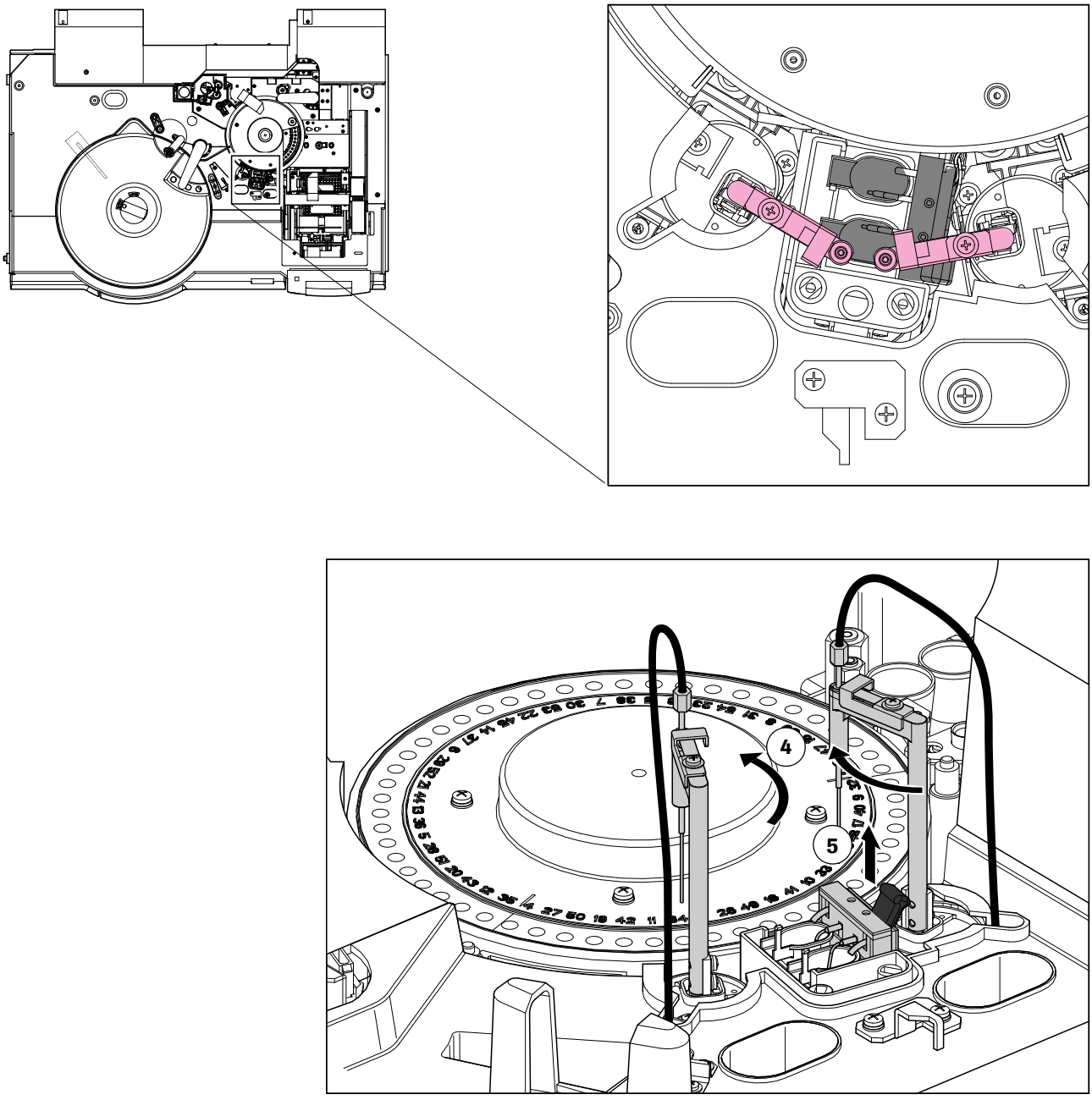
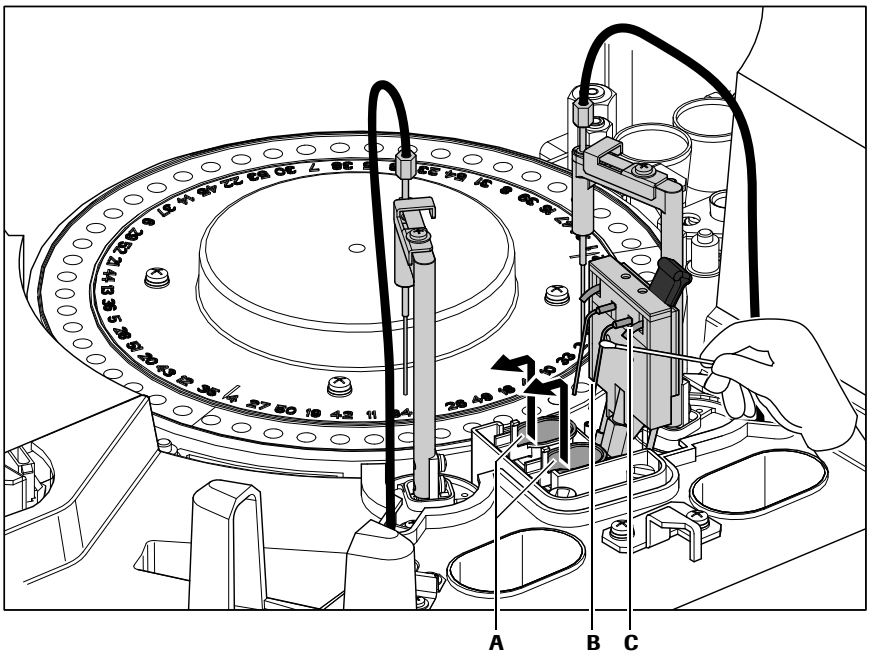


Figure C-47 Move the sipper probes over the incubator

4 Manually move the sipper probes over the incubator.

5 Pull up the unit containing the PC/CC supplier nozzles and the electrodes using the black handle gently to the stop/hold position.



A Reservoirs
B Reservoir filling nozzle
C Electrodes

Figure C-48 Cleaning ProCell/CleanCell reservoir filling nozzle

6 Clean the ProCell/CleanCell reservoir filling nozzle (**B**) and electrodes (**C**) by wiping them with cotton tipped applicator stick soaked in deionized water.

■

► Procedure 3 – To replace ProCell/CleanCell reservoirs

1 Carefully remove the ProCell/CleanCell reservoirs (**A**) (upward /left direction) making sure the electrodes are not bent.

2 Clean the inside of the reservoir positions by wiping them with cotton tipped applicator stick soaked in deionized water.

3 Place new reservoirs in the reservoir positions and push the sipper nozzle unit back into place.

4 Close the top cover and lock it with the key.

5 Choose **Stop** (global button) once cleaning is complete.

6 Choose **Yes** to stop maintenance after confirmation.

■

► Procedure 4 – To perform Reagent Prime

1 Choose **Utility** > **Maintenance**.

2 Choose **(8) Reagent Prime** in the **Maintenance** Items list.

3 Choose **Select** to display the **Reagent Prime** window.

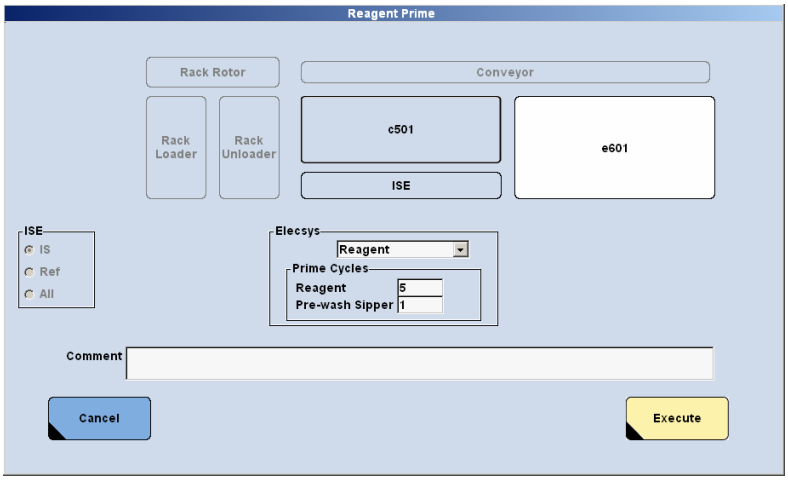


Figure C-49 Reagent Prime window

4 Deselect the **c** 501 module and select the **e** 601 module.

5 In the **Elecsys** area select **Reagent** from the **e** 601 list box. In the **Prime Cycles** area enter 1 for the **Reagent**

6 Choose **Execute** to start reagent priming.

7 Wait until the reagent prime is completed and the instrument enters standby mode, then start finalization.

If, after the maintenance is performed, the instrument is to be powered off or in standby for an extended period of time then a finalization must be performed.

If further samples are to be processed then finalization is not necessary.

■

► Procedure 5 – To perform Finalization

1 Choose **Utility** > **Maintenance**.

2 Choose **(32) Finalization** in the **Maintenance** Items list.

3 Choose **Select** to display the **Finalization** window.

4 Select the appropriate **e** 601 module and deselect all other modules and units. Selected modules are highlighted in white. Channel 1+2 is activated.

5 Choose **Execute** to start finalization. The procedure is complete when the system returns to standby.

■

Cleaning mixing station and separation stations of the Pre-wash area

Spills on the mixing station and the separation stations could cause gripper movement alarms.

Operator time approximately 5 minutes

Materials required
- ☐ Cotton tipped applicator sticks
- ☐ Lint-free gauze squares
- ☐ Deionized water

► To clean Pre-wash mixer and separation station

1. Choose **Utility** > **Maintenance**.
2. Choose **Maintenance** on the **Maintenance Type** list.
3. Choose **(29) Manual Cleaning** on the **Maintenance** Items list.
4. Choose **Select** to display the **Manual Cleaning** window.
5. Select the appropriate **e** 601 module and deselect all other modules and units. Selected modules are highlighted in white.
6. Choose **Execute**. The probes on the selected module(s) move to their cleaning positions. After all movement has stopped, manual cleaning can begin.
7. Touch a screw on the rack sampler unit in order to ground any static charge which may have built-up on you.

8 Open the top cover of the **e** 601 module to be cleaned.

Damage to the probes

Do not bend or damage the lower end of the sipper and dispenser probes during cleaning.

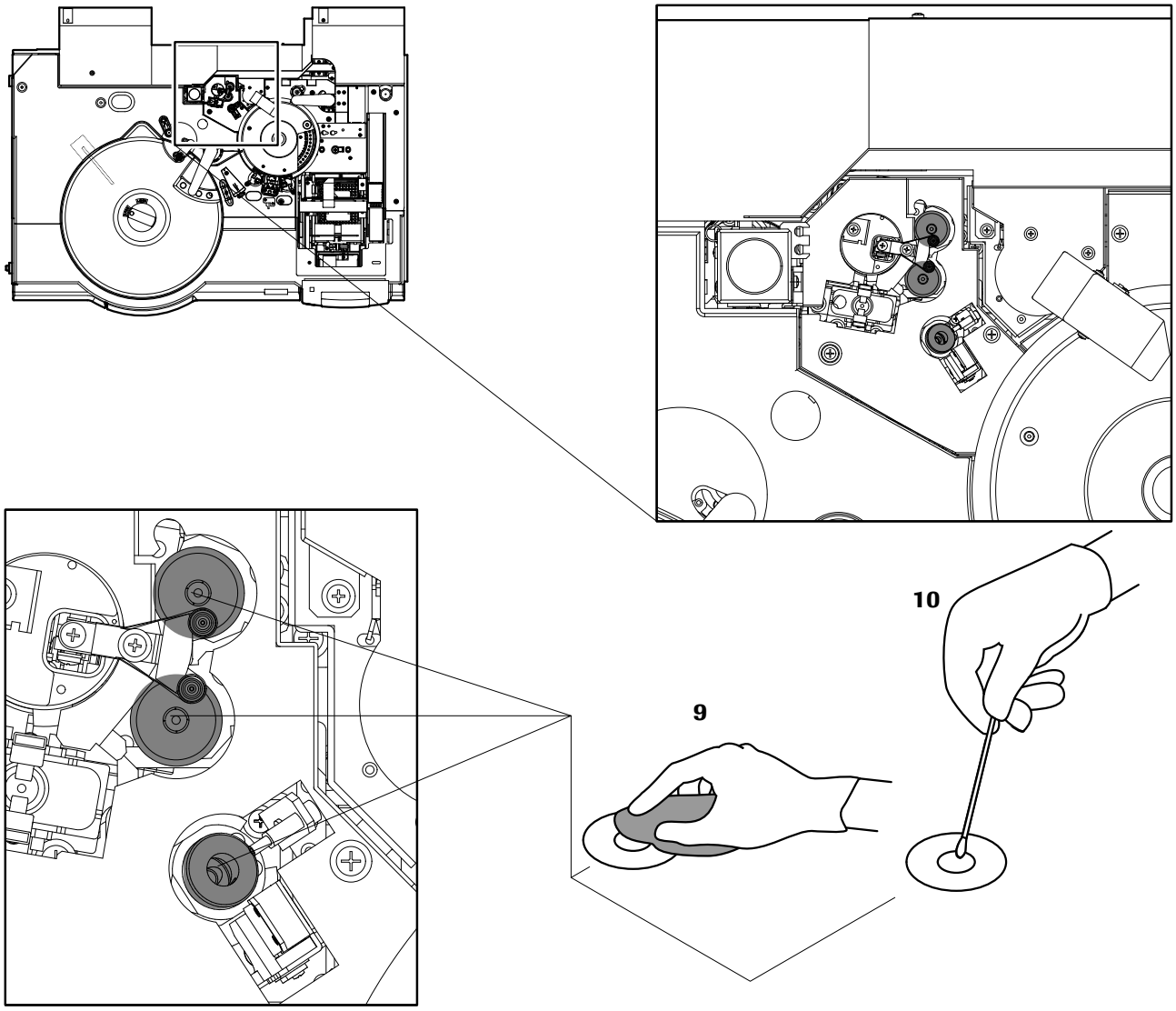


Figure C-50 Cleaning mixing station and separation station

9 Clean the surface of the mixing station and the separation stations with lint-free gauze squares dampened with deionized water. If the mixing station and the separation stations appear dirty, use a slight scrubbing motion with the water-soaked lint-free gauze squares.

10 Next, wet cotton tipped applicator sticks with deionized water and swab the openings on the mixing station and the separation stations.

11 Dry the mixing station and the separation stations with dry lint-free gauze squares and cotton tipped applicator sticks when cleaning is completed.



Ensure that the surface and the openings of the mixing station and the separation stations are dry and not clogged or the gripper may experience problems when operation is resumed.

12 Close the cover and lock it with the key.

13 Choose **Stop** (global button) once cleaning has been completed.

14 Choose **Yes** to stop maintenance after confirmation.

■

► To return mechanical parts to standby position

1 Choose **Utility** > **Maintenance**.

2 Select **Maintenance** from the **Maintenance Type** list.

3 Select **(1) Reset** from the **Maintenance** Items list.

4 Choose **Select** to display the **Reset** window.

5 Select the appropriate **e** 601 module and deselect all other modules and units. Selected modules are highlighted in white.

6 Choose **Execute**. Mechanical parts on the selected **e** 601 module move to their standby positions.

■

Cleaning incubator

Spills on the incubator could cause gripper movement alarms.

Operator time approximately 10 minutes

Materials required
- ☐ Lint-free gauze squares
- ☐ Cotton tipped applicator sticks
- ☐ Deionized water

► To clean the incubator

1. Choose **Start** (global button) > **Masking** > **Module Masking** to display the **Module Masking** screen.
2. Select the **e** 601 module you wish to mask and choose **OK**. The selected **e** 601 module is now masked and goes into standby mode.
3. Touch a screw on the rack sampler unit in order to ground any static charge which may have built-up on you.

4 Open the top cover and move the gripper manually if necessary, to allow the incubator cover to be removed.

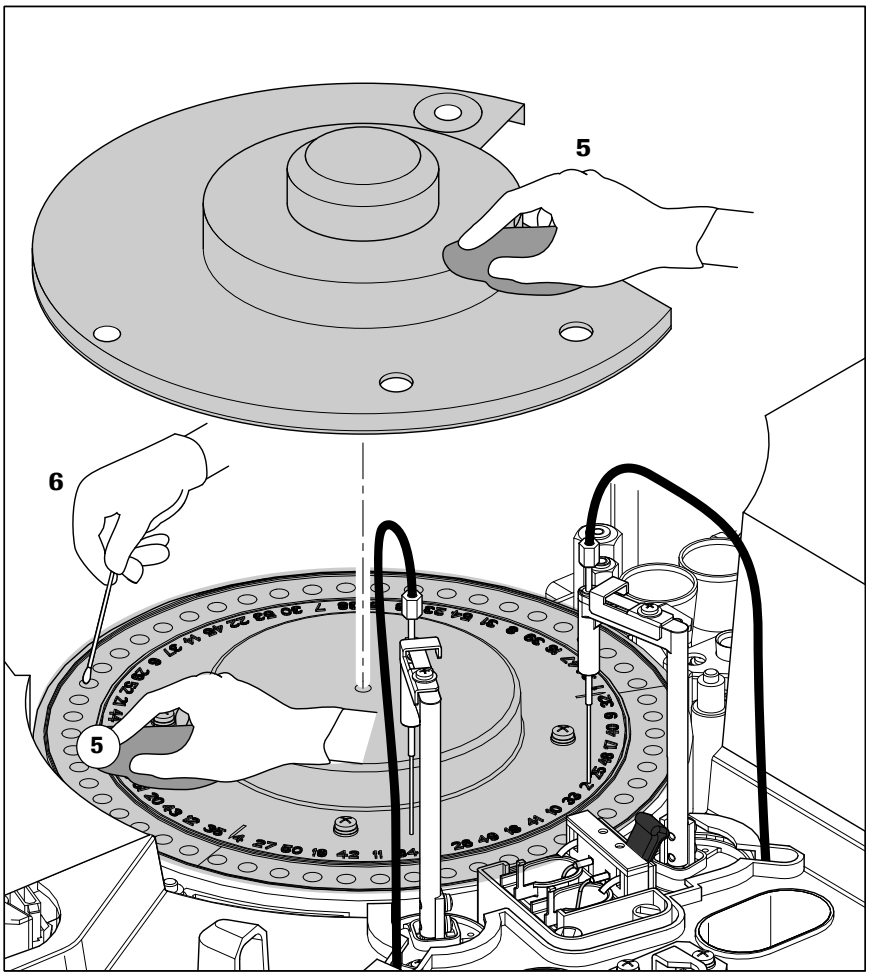


Figure C-51 Cleaning incubator

5 Clean the incubator cover and the top of the incubator with lint-free gauze squares dampened with deionized water. If the incubator or the cover appears dirty, use a slight scrubbing motion with the water-soaked lint-free gauze squares.

6 Next, wet cotton tipped applicator stick with deionized water and swab each of the 54 positions on the incubator.

7 Dry the incubator with dry lint-free gauze squares and cotton tipped applicator sticks when cleaning is completed.

Ensure that the incubator and its positions are dry and not clogged or the gripper may experience problems when operation is resumed.

8 Replace the incubator cover, close the top cover and lock it with the key.

9 Unmask the module at **Start** (global button) > **Masking** > **Module Masking**.

■

Cleaning vortex mixing station

Spills on the vortex mixing station for AssayCups could cause gripper movement alarms.

Operator time approximately 2 minutes

Materials required
- ☐ Lint-free gauze squares
- ☐ Cotton tipped applicator sticks
- ☐ Deionized water

► To clean the vortex mixing station

1. Choose **Utility** > **Maintenance**.
2. Choose **Maintenance** on the **Maintenance Type** list.
3. Choose **(29) Manual Cleaning** on the **Maintenance** Items list.
4. Choose **Select** to display the **Manual Cleaning** window.
5. Select the appropriate **e** 601 module and deselect all other modules and units. Selected modules are highlighted in white.
6. Choose **Execute**. The probes on the selected module(s) move to their cleaning positions. After all movement has stopped, manual cleaning can begin.

7 Touch a screw on the rack sampler unit in order to ground any static charge which may have built-up on you.

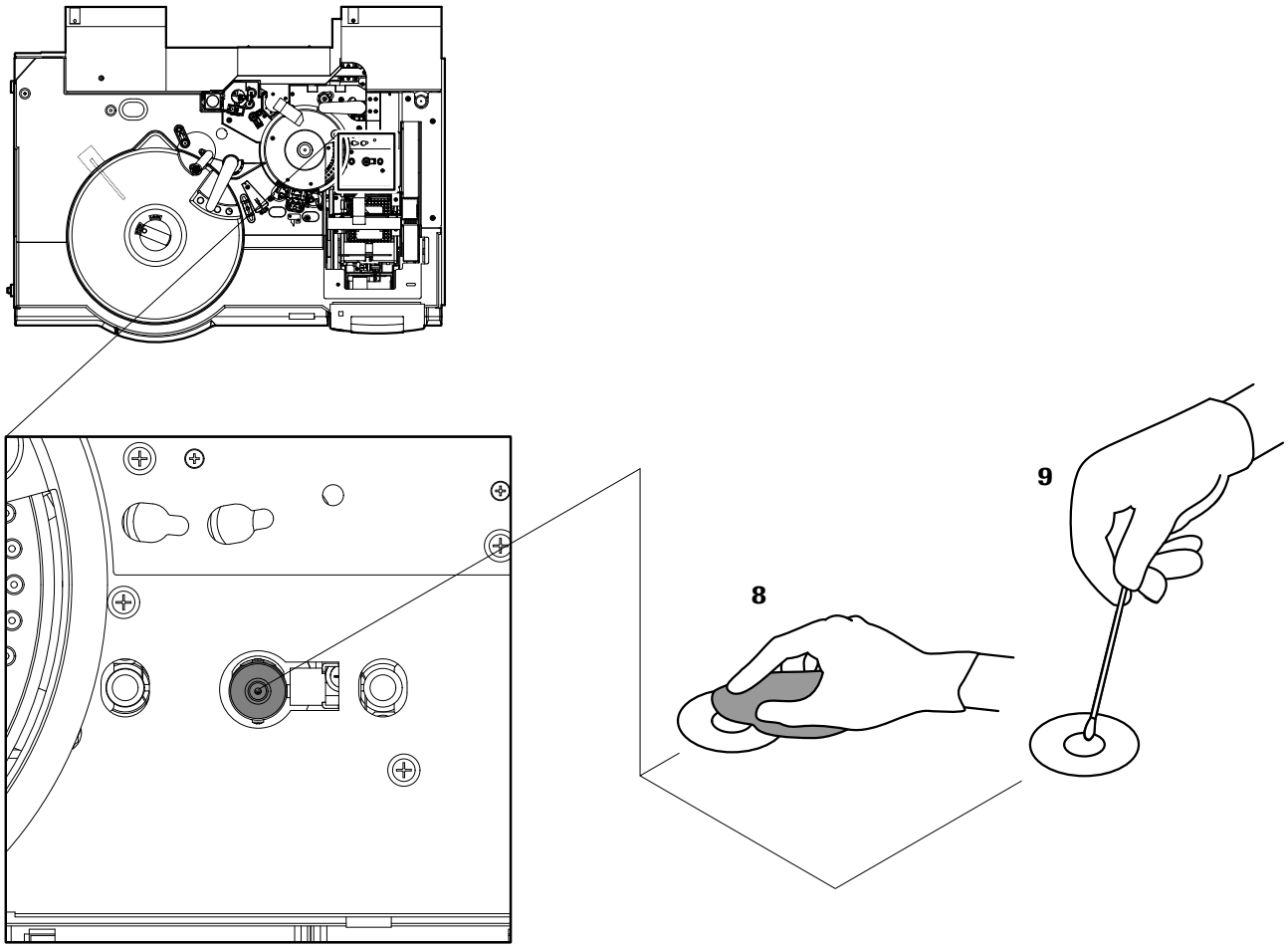


Figure C-52 Cleaning vortex mixing station

8 Clean the surface of the vortex mixing station with lint-free gauze squares dampened with deionized water. If the vortex mixing station appears dirty, use a slight scrubbing motion with the water-soaked lint-free gauze squares.

9 Wet cotton tipped applicator stick with deionized water and swab the opening of the vortex mixing station.

10 Dry the vortex mixing station with dry lint-free gauze squares and cotton tipped applicator sticks when cleaning is completed.

Ensure that the vortex mixing station and its opening are dry and not clogged or the gripper may experience problems when operation is resumed.

11 Close the top cover and lock it with the key.

12 Choose **Stop** (global button).

13 Choose **Yes** to stop maintenance after confirmation.

■

► **To return probes to standby positions**

1. Choose **Utility** > **Maintenance**.
2. Select **Maintenance** from the **Maintenance Type** list.
3. Select **(1) Reset** from the **Maintenance** Items list.
4. Choose **Select** to display the **Reset** window.
5. Select the appropriate **e** 601 module and deselect all other modules and units. Selected modules are highlighted in white.
6. Choose **Execute**. The probes on the selected **e** 601 module move to their standby positions.

■

Cleaning microbead mixer

Impurities on the microbead mixer may cause problems, and affect results.

Operator time approximately 2 minutes

Materials required
- ☐ Lint-free gauze squares
- ☐ Alcohol (e.g. isopropyl alcohol or ethanol)
- ☐ Deionized water
- ☐ Small Brush

► **To clean the microbead mixer**

1. Choose **Utility** > **Maintenance**.
2. Choose **Maintenance** on the **Maintenance Type** list.
3. Choose **(29) Manual Cleaning** on the **Maintenance** Items list.
4. Choose **Select** to display the **Manual Cleaning** window.
5. Select the appropriate **e** 601 module and deselect all other modules and units. Selected modules are highlighted in white.
6. Choose **Execute**. The probes on the selected module(s) move to their cleaning positions. After all movement has stopped, manual cleaning can begin.
7. Touch a screw on the rack sampler unit in order to ground any static charge which may have built-up on you.

8 Open the top cover.

Damage to the microbead mixer

- Do not bend the microbead mixer during cleaning.
- Look and make sure the microbead mixer is not bent.

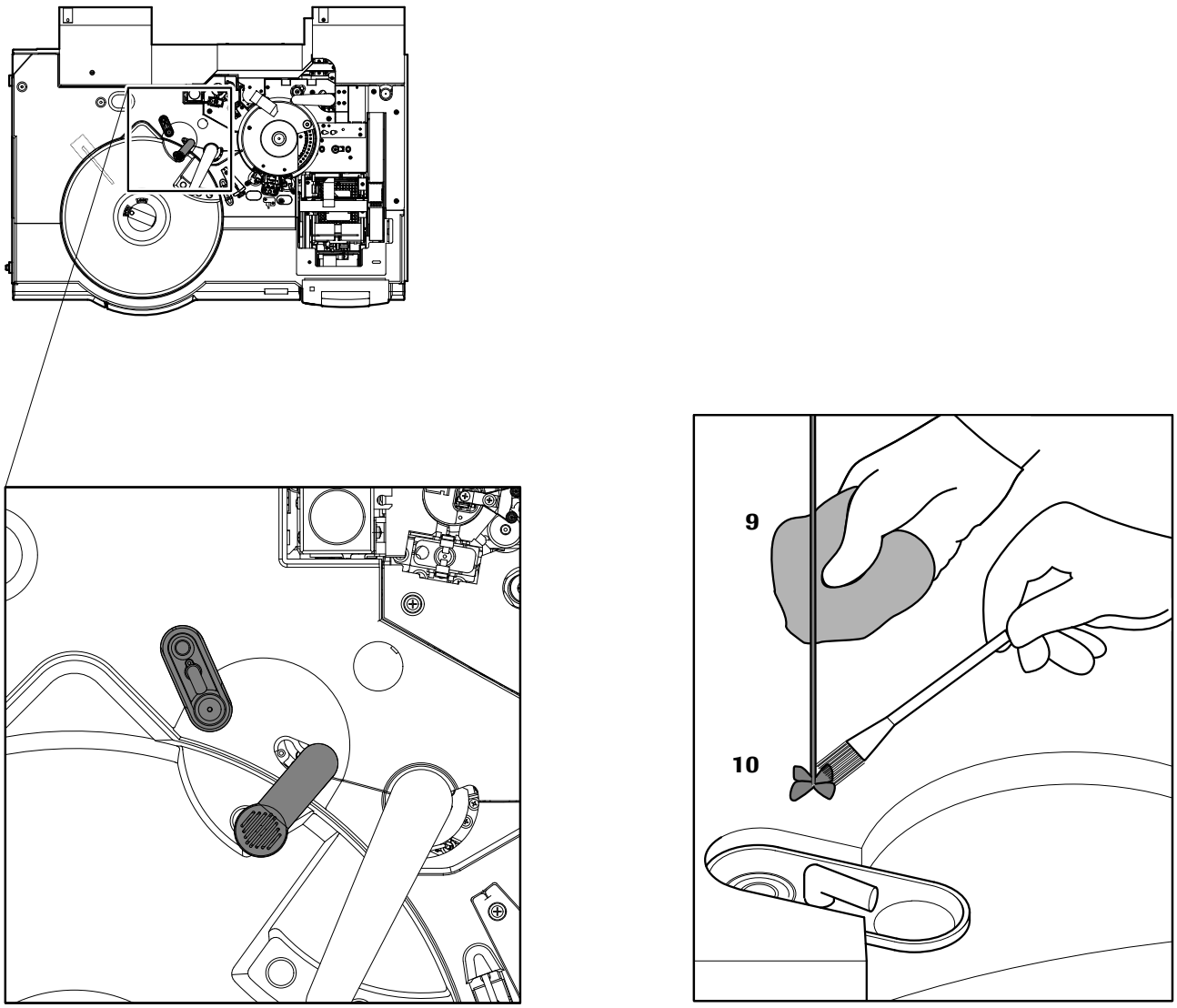


Figure C-53 Cleaning microbead mixer

9 Very carefully wipe the microbead mixer paddle with lint-free gauze square soaked in alcohol from top to bottom.

10 Use a brush to clean the 4 propeller plates with alcohol.

11 Repeat the procedure using deionized water instead of alcohol.

12 Choose **Stop** (global button).

13 Choose **Yes** to stop maintenance after confirmation.

■

► **To return probes to standby positions**

1. Choose **Utility** > **Maintenance**.
2. Select **Maintenance** from the **Maintenance Type** list.
3. Select **(1) Reset** from the **Maintenance** Items list.
4. Choose **Select** to display the **Reset** window.
5. Select the appropriate **e** 601 module and deselect all other modules and units. Selected modules are highlighted in white.
6. Choose **Execute**. The probes on the selected **e** 601 module move to their standby positions.

■

Cleaning rinse stations

Contamination in the rinse stations for the Pre-wash probes, the reagent probe, the microbead mixer, and the sipper probes can cause problems.

Operator time approximately 5 minutes

Materials required
- ☐ Cotton tipped applicator sticks
- ☐ Alcohol (e.g. isopropyl alcohol or ethanol)
- ☐ 2% EcoTergent
- ☐ 50 mL syringe with tubing attached

► **To clean rinse stations**

1. Choose **Utility** > **Maintenance**.
2. Choose **Maintenance** on the **Maintenance Type** list.
3. Choose **(29) Manual Cleaning** on the **Maintenance** Items list.
4. Choose **Select** to display the **Manual Cleaning** window.
5. Select the appropriate **e** 601 module and deselect all other modules and units. Selected modules are highlighted in white.

6 Choose **Execute**. The probes on the selected module(s) move to their cleaning positions. After all movement has stopped, manual cleaning can begin.

7 Touch any screw on the rack sampler unit in order to ground any static charge which may have built-up on you.

8 Open the top cover.

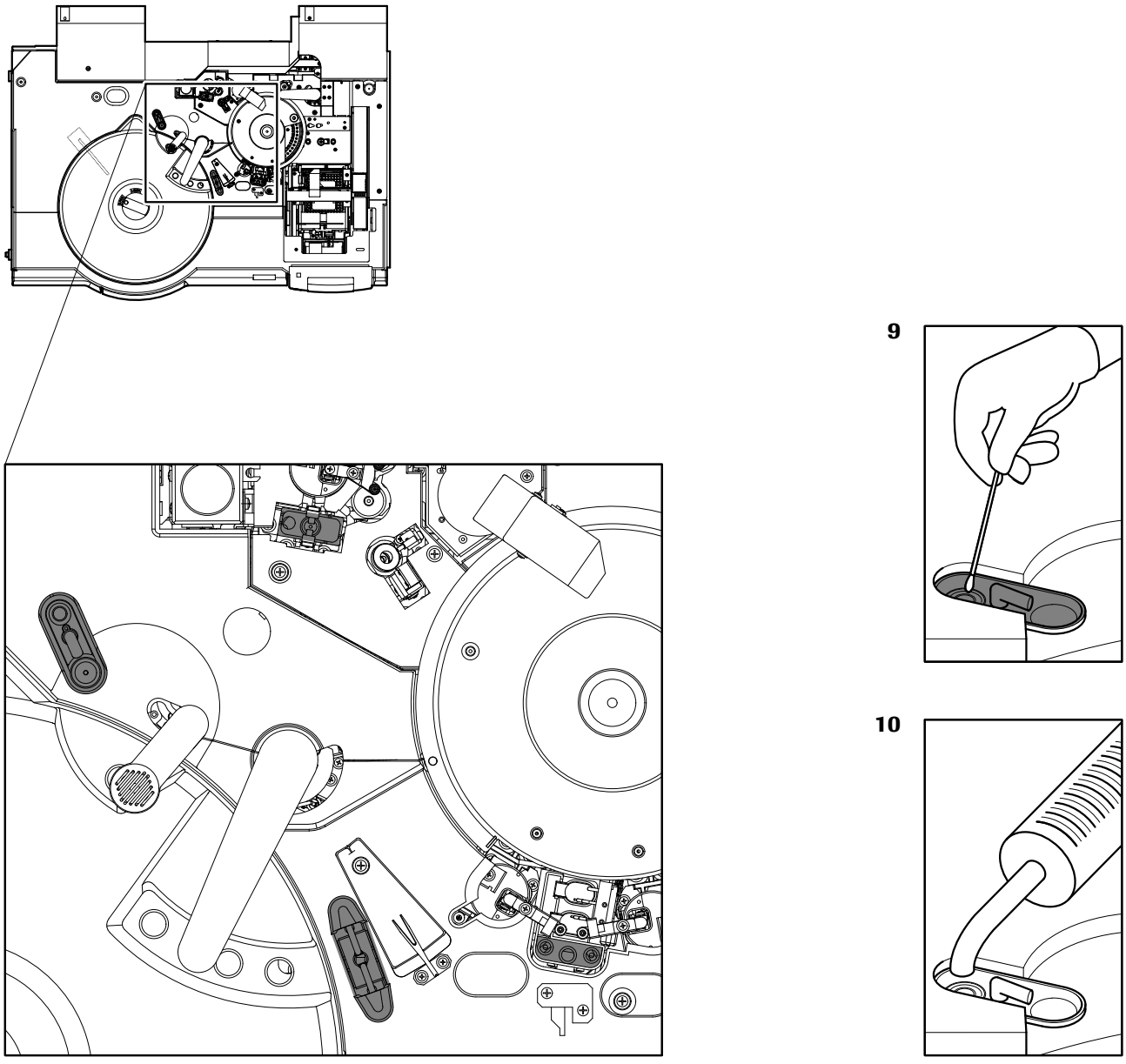


Figure C-54 Cleaning Pre Wash rinse station

9 Clean the inside of each rinse station using cotton tipped applicator stick soaked in alcohol, followed by cotton tipped applicator stick soaked in deionized water.

10 Fill a syringe (with tubing attached) with 50 mL of 2% EcoTergent.

11 Inject the EcoTergent solution (empty the syringe) into the drain hole of the rinse bath.

12 Fill a syringe with 50 mL deionized water.

13 Inject the deionized water (empty the syringe) into the drain hole of the rinse bath.

14 Repeat step 1-13 for all of the probe and stirrer rinse baths on each **e** 601 module.

15 Choose **Stop** (global button).

16 Choose **Yes** to stop maintenance after confirmation.

■

► To return probes to standby positions

1 Choose **Utility** > **Maintenance**.

2 Select **Maintenance** from the **Maintenance Type** list.

3 Select **(1) Reset** from the **Maintenance** Items list.

4 Choose **Select** to display the **Reset** window.

5 Select the appropriate **e** 601 module and deselect all other modules and units. Selected modules are highlighted in white.

6 Choose **Execute**. The probes on the selected **e** 601 module move to their reset positions.

■

Every two weeks maintenance

In this section you find all the maintenance for the **e** 601 module that must be performed at least once every two weeks.

Liquid flow path cleaning

Contamination in the sipper system could cause problems. To keep the flow paths of the sippers clean and maintain the integrity of the measuring cell, perform liquid flow path cleaning at least every two weeks or after 2500 to 3000 determinations per channel, whichever comes first.

See *Cumulative Operation List* on page E-158.

Operator time approximately 5 minutes

System time approximately 30 minutes

Materials required
- ☐ 2 SysClean Adapter M
- ☐ SysClean solution

► To prepare Liquid Flow Path Cleaning

1 Open the top cover.

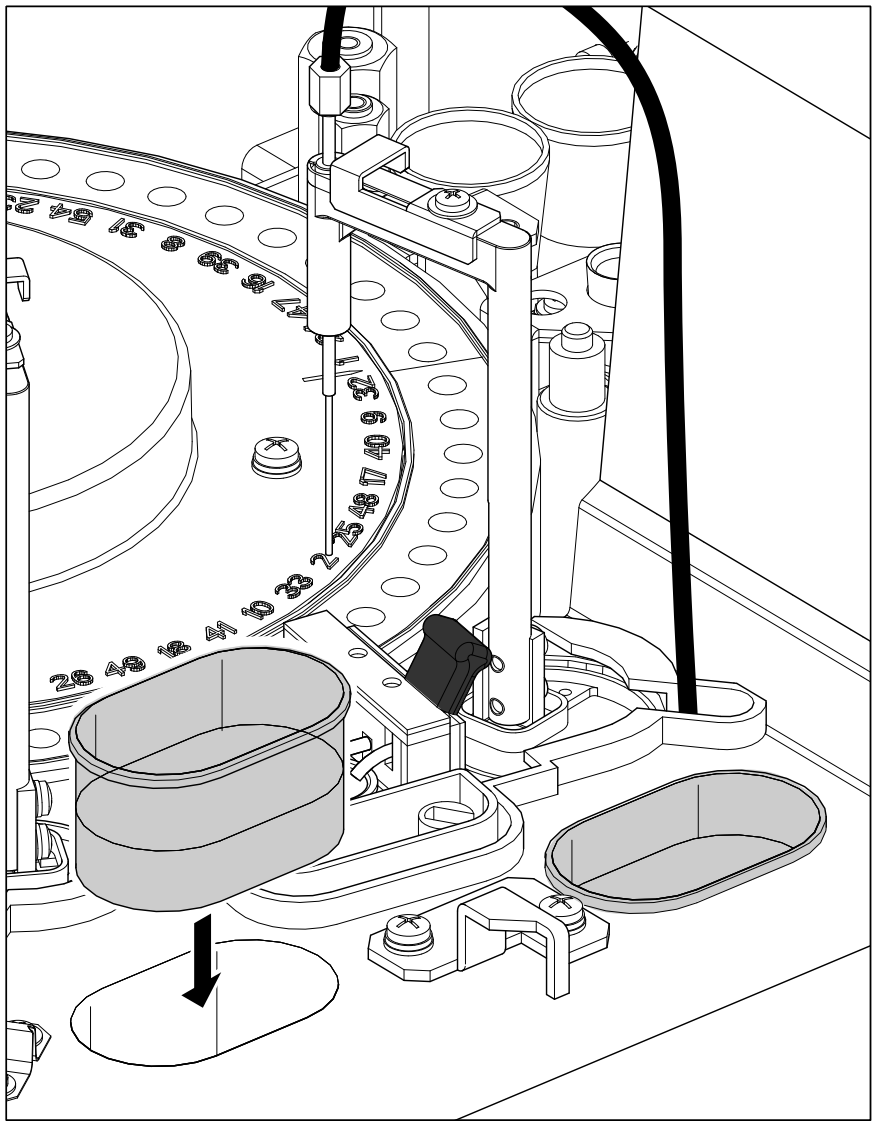


Figure C-55 Placing SysClean Adapter M

2 Fill the SysClean Adapter M with SysClean solution to the lower line (approximately 9 mL/cup).

3 Carefully, insert the filled SysClean cups into the position located in front of the sipper unit to be cleaned.

4 Close the top cover.

■

► To initiate Liquid Flow Path Cleaning

1. Choose **Utility** > **Maintenance**.
2. Select **Maintenance** from the **Maintenance Type** list.
3. Select **(27) Liquid Flow Cleaning** from the **Maintenance** Items list.
4. Choose **Select** to display the **Liquid Flow Path Cleaning** window.
5. Select the appropriate **e** 601 module and deselect all other modules. Selected modules are highlighted in white.
6. Select the Ch1,2 option and enter 1 in the Cycles text box and choose **Execute**.

■

► Post-cleaning steps

1. Open the top cover.
2. Remove the SysClean Adapter M.
3. Dispose of any remaining SysClean solution. Rinse the SysClean Adapter M(s) thoroughly with deionized water.

■

Every three months maintenance

In this section you find all the maintenance for the **e** 601 module that must be performed at least once every three months.

Replacing e 601 pinch valve tubing

Pinch valve tubings wear out in the course of time. To rule out the risk of defective tubings replace **e** 601 pinch valve tubings every 3 months or after measuring 25,000 tests per measuring cell.

Operator time approximately 5 minutes

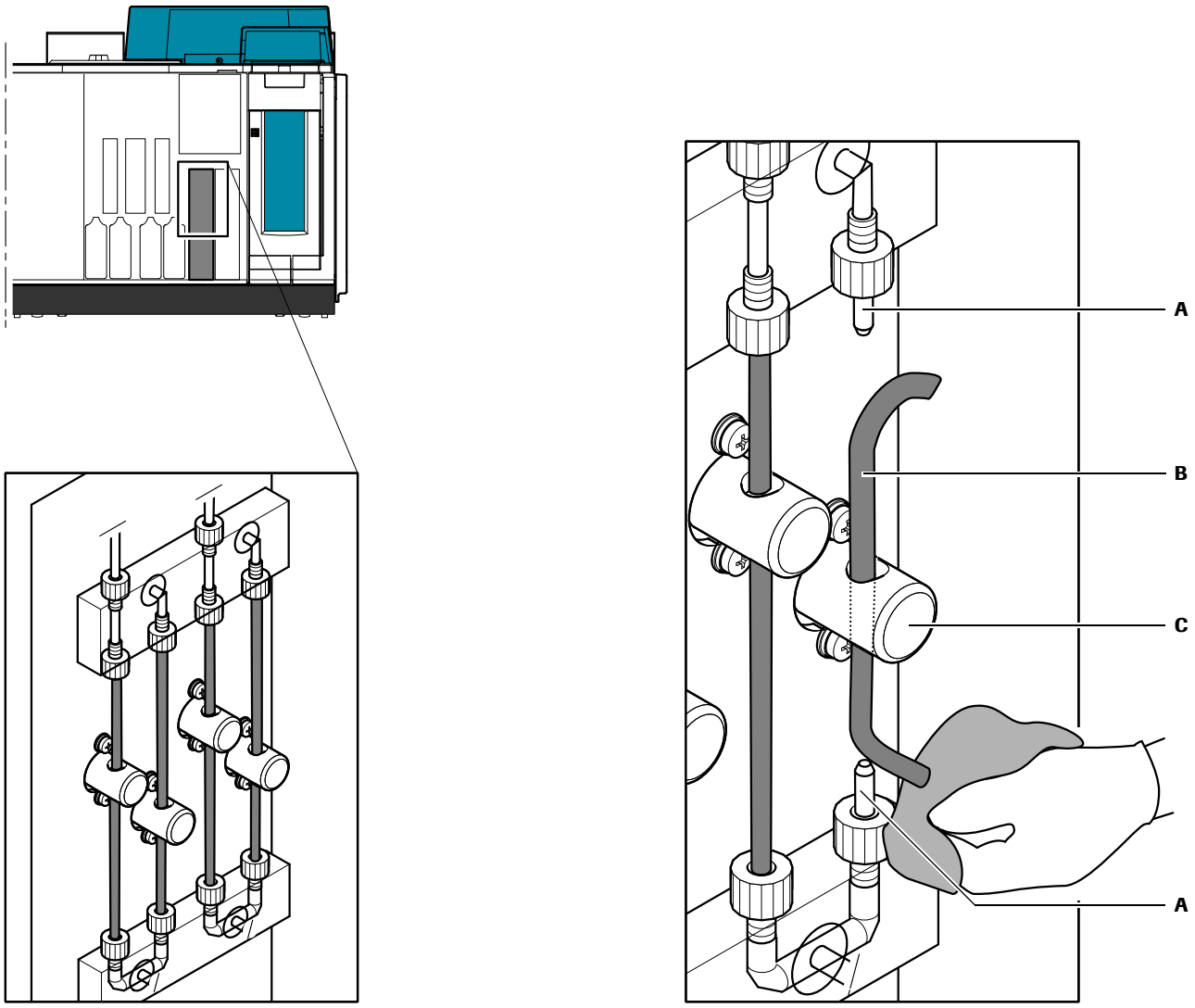
System time approximately 30 minutes

Materials required
- ☐ Pinch valve tubing
- ☐ Lint-free gauze pads
- ☐ Protective equipment (gloves, paper towels)

► To replace e 601 pinch valve tubings

1. Perform maintenance item (26) MC Exchange before removing the tubes, to avoid dripping of fluid on the valves.
2. Shut down the system or put the **e** 601 module into standby mode.

3 Locate the **e** 601 pinch valve tubings behind the front door of the **e** 601 module.



A Tube fitting **B** Tube **C** Pinch valve

Figure C-56 Replacing **e** 601 pinch valve tubing

4 Carefully remove (pull) all 4 pinch valve tubings (**B**) from the fittings (**A**).

5 Use a dry gauze pad to absorb liquid which drains from the acrylic block or from the tubing.

6 Take new pinch valve tubing and insert it through the pinch valve (**C**).

7 Carefully slide the ends of the tubing over each fitting (**A**).

■

After replacement of the **e** 601 pinch valve tubing it is necessary to perform 2 maintenance items before resuming operation:

- (24) Sipper Air Purge
- (25) MC Preparation

► To perform Sipper Air Purge

1. Start up the instrument.
2. After initialization is finished, choose **Utility** > **Maintenance**.
3. Select **(24) Sipper Air Purge** from the **Maintenance** Items list on the right and choose **Select** to display the **Sipper Air Purge** window.
4. Select the appropriate **e** 601 module and deselect all other modules and units. Selected modules are highlighted in white.
5. Enter 10 in the **Cycles** box and choose **Execute** to initiate the Sipper Air Purge.

 While the air purge is executed, inspect the syringe to ensure that no air remains in the syringe and no leaks are visible at any of its fittings. Also check that the sufficient amount of water is discharged from the sipper probe.

■

► To perform MC Preparation

1. After sipper air purge is finished, select **(25) MC Preparation** from the **Maintenance** Items list on **Utility** > **Maintenance**.
2. Choose **Select** to display the **MC Preparation** window.
3. Select the appropriate **e** 601 module and deselect all other modules and units. Selected modules are highlighted in white.
4. Under **Channel** select **Ch1,2**. If only one tube has been replaced, choose the appropriate measuring channel.
5. Enter 10 in the **Cycles** box and choose **Execute** to initiate the maintenance function.

 Again, check for leaks at the fittings and on the tubings while the system is performing the maintenance function.

■

As needed

In this section you find all the maintenance for the **e** 601 module that must be performed as needed and are not subject to a regular time schedule.

Cleaning ProCell/CleanCell stand and aspiration tubes

Clean ProCell and CleanCell stand and aspiration tubes if crystallization is observed.

Operator time approximately 5 minutes

System time 15 minutes

Materials required
- ☐ Lint-free gauze squares
- ☐ ProCell/CleanCell bottle caps
- ☐ Paper towels
- ☐ Deionized water

As needed

► To clean ProCell/CleanCell stand and aspiration tubes

1 Open the middle door of the **e** 601 module to be cleaned.

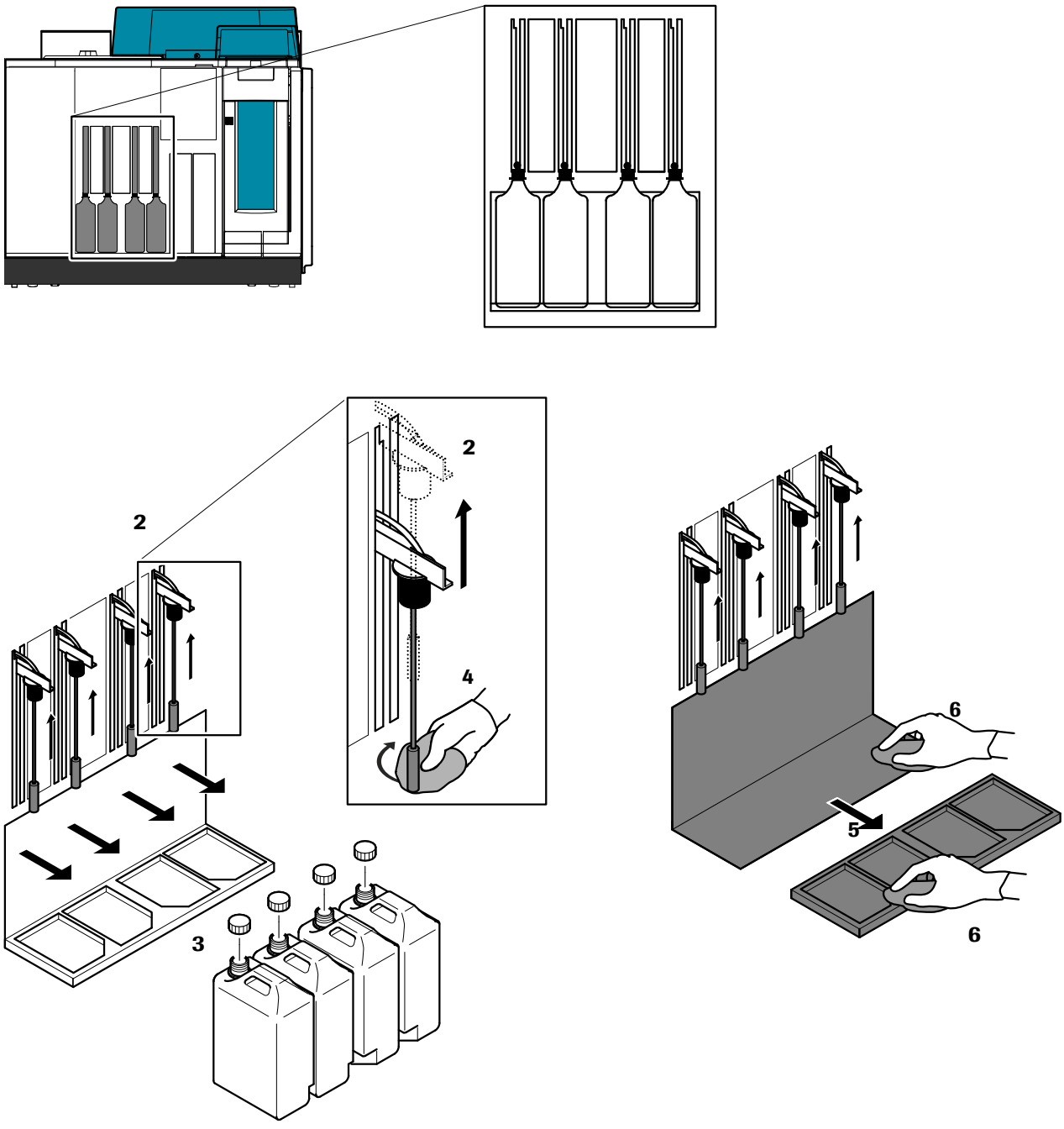


Figure C-57 Cleaning ProCell/CleanCell stand and aspiration tubes

2 Pull the aspiration tubes up and to the left to secure them on their respective notches.

3 Cap the ProCell and CleanCell reagent bottles and remove them from the **e** 601 module.

Droplets of ProCell and CleanCell may drip when ProCell and CleanCell bottles are removed. If this occurs, use paper towels to wipe up the liquid.

4 Wipe the aspiration tubes with lint-free gauze squares soaked with deionized water and then dry them with dry lint-free gauze squares.

5 Remove the ProCell and CleanCell stand from the module.

6 Clean the stands with lint-free gauze squares soaked with deionized water and then dry them with dry lint-free gauze squares.

7 It may be necessary to clean inside the instrument surface. Use lint-free gauze square with water and dry after.

CAUTION! False results due to ProCell/CleanCell bottle misplacement. ProCell and CleanCell bottles are different in shape to fit the keyed position of the bottle stand.

8 Replace the ProCell and CleanCell stand in the module.

9 Replace the ProCell and CleanCell reagent bottles in their original positions and remove the caps.

CAUTION! False results due to loose ProCell/CleanCell aspiration tube filters. Make sure the aspiration tube is pulled up and hooked on to its notch, before removing the bottle. After replacing the bottle, unhook the aspiration tube and lower it slowly into the bottle, do not let it drop into the bottle.

10 Guide the aspiration tubes into the bottles.

11 Close the middle door of the **e** 601 module.

■

As needed

Cleaning reagent disk and compartment

Clean reagent spills as they occur. Clean the reagent disk as needed.

Operator time approximately 10 minutes

Materials required
- ☐ Lint-free gauze squares
- ☐ Alcohol (e.g. isopropyl alcohol or ethanol)
- ☐ Deionized water
- ☐ Cloth or lint-free towels

► To remove reagent disk and clean the reagent disk and compartment

1 Ensure the system is in standby.

Damage to the microbead mixer

- Do not bend the microbead mixer when cleaning the reagent disk compartment.
- Avoid contact with the microbead mixer when removing and replacing the cover and reagent disk.

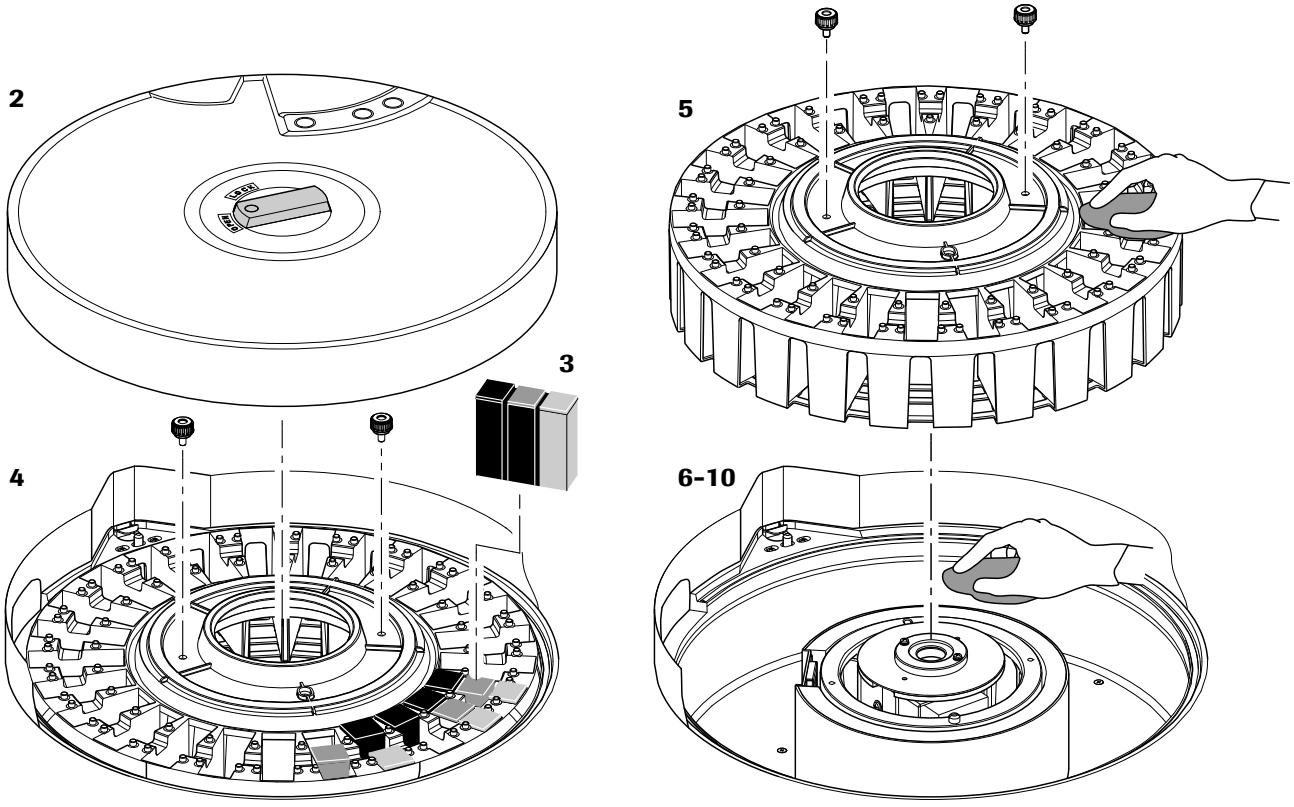


Figure C-58 Cleaning reagent disk and compartment

2 Remove the cover from the reagent disk.

3 Completely close the **cobas e** pack caps and remove all the **cobas e** packs from the reagent disk.

4 Loosen and remove the black thumbscrews.

5 Remove the reagent disk from the compartment.

6 Wipe the inside and outside of the reagent disk with lint-free gauze squares soaked with deionized water.

7 If the disk appears dirty, use lint-free gauze squares soaked with alcohol to clean the disk. Follow with lint-free gauze squares soaked with deionized water.

8 Dry the reagent disk with a cloth or lint-free towels. Set the reagent disk aside.

Do not scratch or smear the barcode reader window as this may cause barcode reading errors.

9 Wipe the reagent disk compartment with lint-free gauze squares soaked with deionized water.

If the compartment appears dirty, use lint-free gauze squares soaked with alcohol to clean the compartment. Follow with lint-free gauze squares soaked with deionized water.

10 Dry the reagent disk compartment with a cloth or lint-free towels.

■

► To reinstall reagent disk

1 Return the reagent disk to the compartment. Make sure that the alignment pin on the center plate is aligned with the opening on the disk.

2 Securely reinstall the thumbscrews.

3 Place the **cobas e** packs back into the reagent disk.

4 Replace the reagent disk cover and lock.

■

As needed

Cleaning solid waste compartment

Check the waste compartment when emptying the solid waste containers. If the compartment is dirty and requires cleaning, follow the procedures below.

Operator time approximately 5 minutes

Materials required
- ☐ Lint-free gauze squares
- ☐ Laboratory disinfectant (no alcohol or bleach)
- ☐ Deionized water
- ☐ WasteLiner M

Damage to the solid waste compartment

Do not use alcohol or bleach to clean the solid waste compartment as this may damage the compartment.

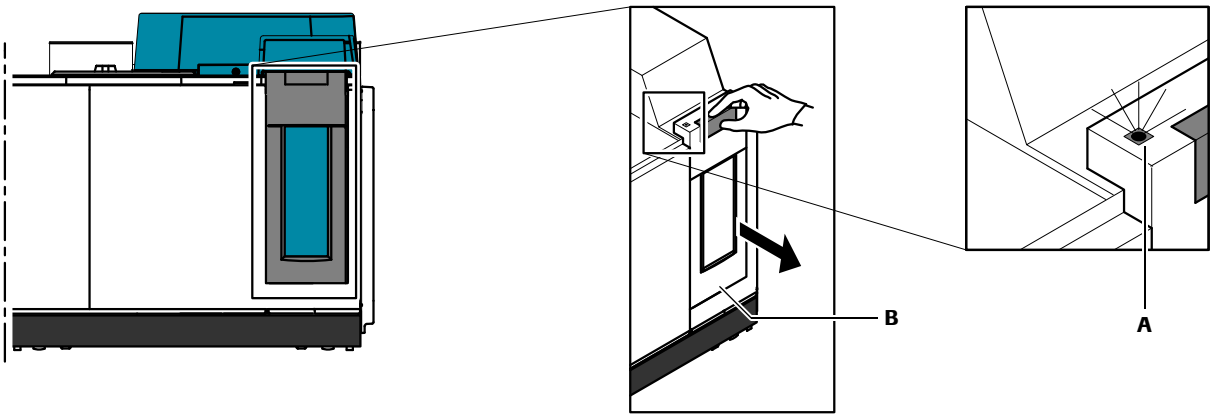
► To clean the solid waste compartment

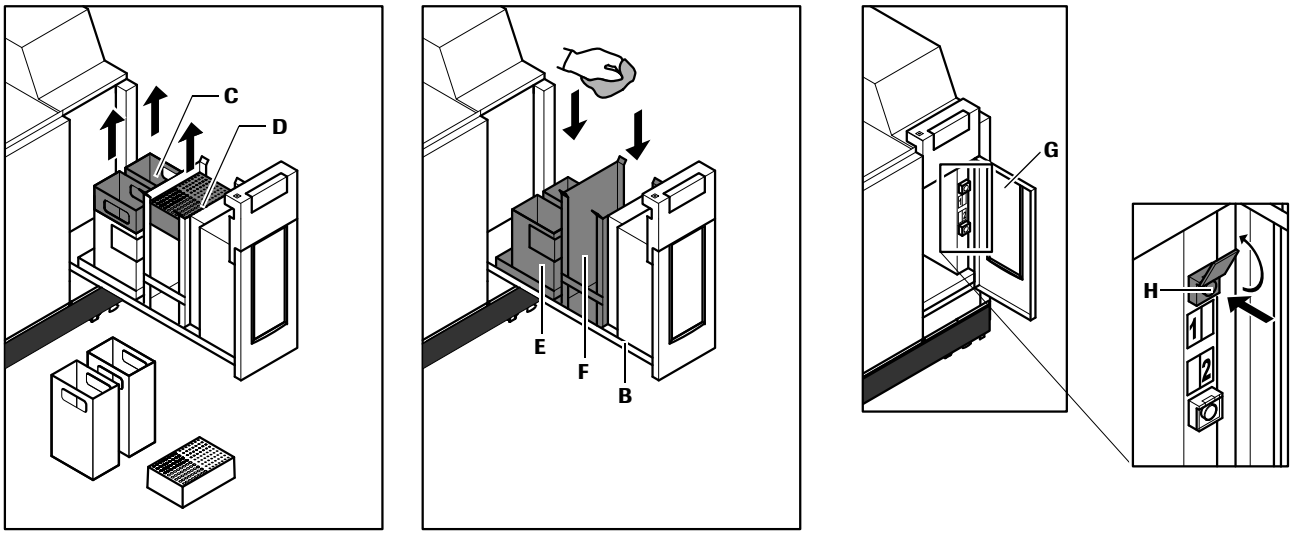
1 Choose **Start** (global button) > **Masking** > **Module Masking** to display the **Module Masking** screen.

2 Select the **e** 601 module which is to be cleaned and choose **OK**. The selected **e** 601 module is now masked and goes into **Module Masking**.

Masking a module prior to performing maintenance ensures that the system does not allocate samples to this module and selectively stops the operation of this module. In this state, the operator can clean the instrument surface safely.

3 Wait until the green indicator lamp (**A**) on the top of the drawer is illuminated, then open the magazine drawer on the right of the module.





A Indicator lamp
B Magazine drawer
C WasteLiners
D Empty magazines
E Solid waste containers
F Magazine waste compartment
G Drawer door
H Green button (for inventory update)

Figure C-59 Consumables area components

4 Open the magazine drawer (**B**) on the right of the module.

5 Remove both WasteLiners (**C**) from the solid waste containers and the empty magazines (**D**) from the magazine waste compartment.

6 Wipe the inside and outside of the solid waste container (**E**) and the magazine waste compartment (**F**) with lint-free gauze squares soaked with disinfectant.

7 Wipe the inside and outside of the solid waste container (**E**) and the magazine waste compartment (**F**) again, this time using lint-free gauze squares soaked with deionized water.

If the area surrounding the waste containers appears to be dirty, it should also be cleaned using the same procedure.

As needed

8 Place new WasteLiners into the waste containers.

9 Close the drawer, ensuring that it is fully closed.

10 Open the transparent door (**G**) at the front of the drawer.

11 Press the green button (**H**) corresponding to the container(s) emptied to update the inventory. These buttons flash for a moment and then light green.

12 Close the door ensuring that it is fully closed.

■

- Ensure that the door at the front of the drawer is closed. Otherwise, the magazine lifter detects the open door the next time it operates and the system stops.
- The inventory is updated and displayed on the **Reagent Overview** window.

Cleaning instrument surfaces

Spills on the instrument surface could be potentially biohazardous and damage the surface.

Operator time approximately 5 minutes

System time 0 minutes

Materials required
- ☐ Cloth or paper towels
- ☐ Laboratory disinfectant (no bleach)

► To clean instrument surfaces

1 Choose **Start** (global button) > **Masking** > **Module Masking** to display the **Module Masking** screen.

2 Select the **e** 601 module you wish to mask and choose **OK**. The selected **e** 601 module is now masked and goes into module masking mode.

3 Touch a screw on the rack sampler unit in order to ground any static charge which may have built-up on you.

4 Open the top cover of the module.

5 Clean the module surfaces using a cloth or paper towel moistened with disinfectant. Clean up all spills immediately. Use this procedure to ensure that surfaces are clean. If necessary, move the probes or units manually to clean the surface.

6 Close the top cover and lock it with the key.

7 Unmask the module at **Start** (global button) > **Masking** > **Module Masking**.

■

Finalization

Finalization allows the module to stand unused for several hours (for example, overnight). The system is primed with water, the measuring cells are filled with ProCell, and the sipper probes are cleaned with water.

Before going into standby mode, the system automatically performs finalization maintenance. Finalization must be manually initiated if finalization was not performed automatically (due to emergency stop, for example) or did not complete (alarm is issued) and the system will stand unused for several hours.

Always start finalization in combination with reagent prime. Never perform finalization alone.

► To perform Reagent Prime

1 Choose **Utility** > **Maintenance**.

2 Choose **(8) Reagent Prime** in the **Maintenance** Items list.

3 Choose **Select** to display the **Reagent Prime** window.

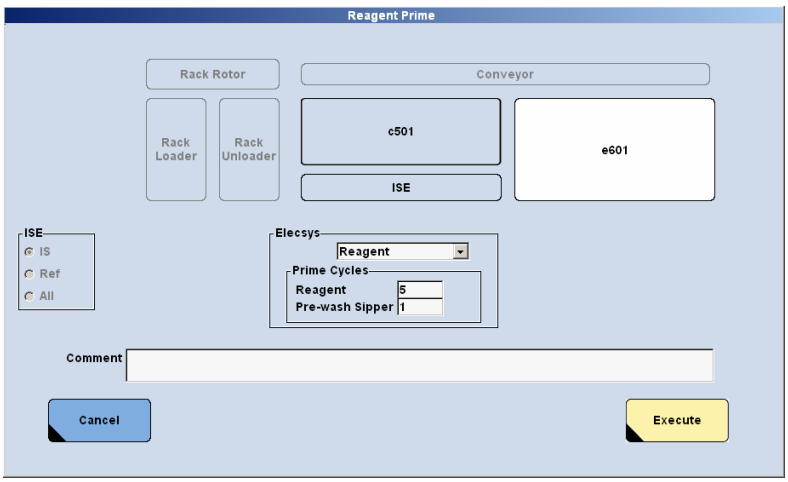


Figure C-60 Reagent Prime window

4 Deselect the **c** 501 module and select the **e** 601 module.

5 In the **Elecsys** area select **Reagent** from the **e** 601 list box. In the **Prime Cycles** area enter 1 for the Reagent.

6 Choose **Execute** to start reagent priming.

7 Wait until the reagent prime completes and the instrument enters standby, then start finalization.

■

As needed

► **To perform Finalization**

1 Choose **Utility** > **Maintenance**.

2 Choose (32) Finalization in the **Maintenance** Items list.

3 Choose **Select** to display the **Finalization** window.

4 Select the appropriate **e** 601 module and deselect all other modules and units. Selected modules are highlighted in white. Channel 1+2 is activated.

5 Choose **Execute** to start finalization.

6 After the procedure has been completed, the system goes into standby.

■

Extended Power OFF procedures

If the system is not used for an extended period of time, it is important to ensure that the system is properly prepared and that the correct shut down maintenance has been performed.

Time period (Days)	Power OFF procedure	Power ON procedure
1 to 2	Power OFF 1	Power ON 1
3 to 7	Power OFF 2	Power ON 2
8 or more	When the instrument was not in use for a period longer than 8 days, call Roche service representative. The necessary procedure is performed by your Roche service representative.	

Table C-29 Extended power OFF procedures

Power OFF 1

Power OFF 1 Use this procedure if the instrument will not be in use for 1 to 2 days (e.g., a weekend).

► **Power OFF 1**

1 Choose **Shut Down** (global button) to display the **Shut Down** window.

2 Select the **Shut Down** option and choose **Execute** to confirm the shutdown.

3 Wait until the computer power supply turns off. Then, switch off the power switch of the printer and monitor.

CAUTION! Damage to the control unit or data loss. Before switching-off of the analyzer, make sure the monitor indication has changed from shutdown to a state where nothing is displayed.

4 Switch off the operation power switch on the left side face of the rack sampler unit.

5 Turn off the water supply.

■

Power OFF 2

Use the following procedure if the instrument will not be used for 3 to 7 days.

System time approximately 45 minutes

The maintenance items listed in this procedure can be programmed as a maintenance pipe.

See *Recommended maintenance pipes* on page C-32.

► To perform Liquid Flow Path Cleaning

For a detailed description of this procedure, see *Liquid flow path cleaning* on page C-137.

1. Open the top cover.
2. Fill the SysClean Adapter M with SysClean solution to the lower line (approximately 9 mL/cup).
3. Carefully, insert the filled SysClean cups into the position located in front of the sipper unit to be cleaned.
4. Close the top cover.
5. Choose **Utility** > **Maintenance**.
6. Select **Maintenance** from the **Maintenance Type** list.
7. Select **(27) Liquid Flow Cleaning** from the **Maintenance** Items list.
8. Choose **Select** to display the **Liquid Flow Path Cleaning** window.
9. Select the appropriate **e** 601 module and deselect all other modules. Selected modules are highlighted in white.
10. Select the Ch1,2 option and enter 1 in the Cycles text box and choose **Execute**.

■

Ensure the system has returned to standby mode before continuing.

As needed

► To remove reagents and consumables

1 Remove the reagent cover and press the caps of each **cobas e** pack down to close them. Remove all **cobas e** packs from the reagent disk(s). Refrigerate them in the same manner as unused **cobas e** packs. The **cobas e** packs can be used again.

2 Remove all magazines from the magazine lifter, and magazine waste. Ensure that no AssayTips or AssayCups are present on the module.

3 Choose **Utility** > **Maintenance**.

4 Select **Check** from the **Maintenance Type** list.

5 Select **(14) Magazine Exchange Check** from the **Maintenance** Items list.

6 Enter 1 in the **Cycle** text box. A caution alarm is issued because there are no AssayTips or AssayCups available.

7 Remove the WasteLiners and replace with fresh ones.

8 Remove the ProbeWash, ProCell, CleanCell and PreClean bottles. Replace them with new bottles filled with deionized water.

9 Remove the SysClean Adapters from the instrument.

■

► To perform Reagent Prime

1 Choose **Utility** > **Maintenance**.

2 Choose **(8) Reagent Prime** in the **Maintenance** Items list.

3 Choose **Select** to display the **Reagent Prime** window.

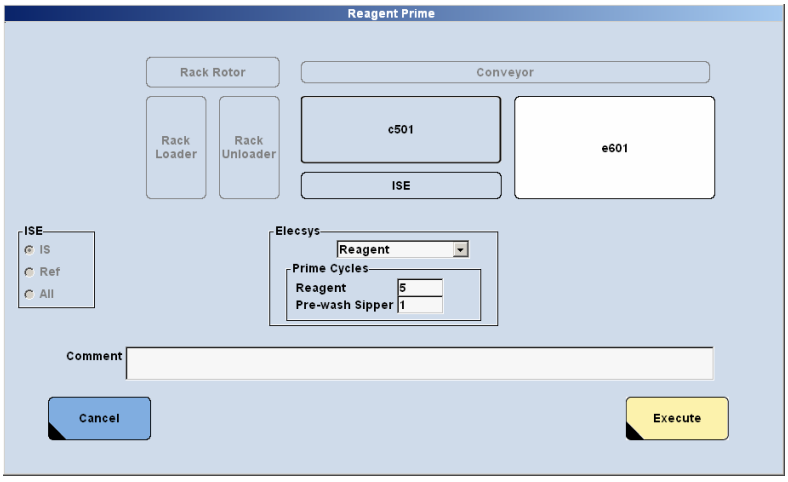


Figure C-61 Reagent Prime window

4 Deselect the **c** 501 module and select the **e** 601 module.

5 In the **Elecsys** area select **Reagent** from the **e** 601 list box. In the **Prime Cycles** area enter 5 for the **Reagent**.

6 Choose **Execute** to start reagent priming.

7 Display the **Reagent Prime** window a second time

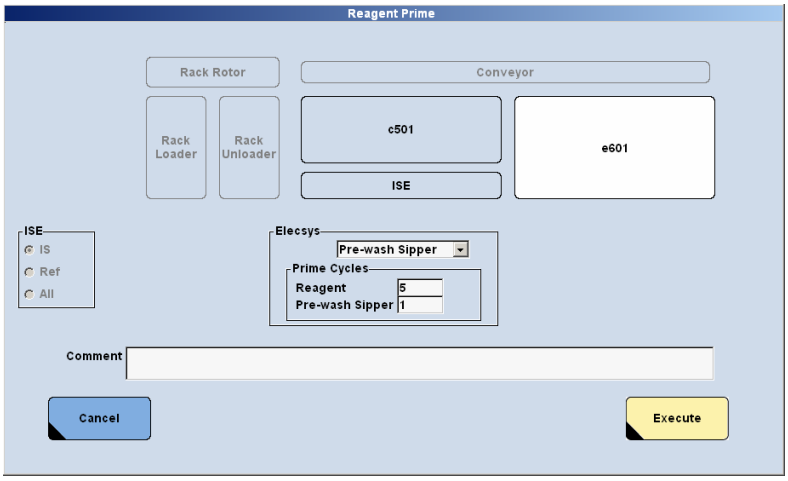


Figure C-62 Reagent Prime window

8 In the **Elecsys** area select **Pre-wash Sipper** from the **e** 601 list box. In the **Prime Cycles** area enter 5 for the **Pre-wash Sipper**

9 Choose **Execute** to start reagent priming.

■

► To empty PC/CC reservoirs

1 Select **(33) Empty PC/CC Reservoir** from the **Maintenance** Items list on **Utility** > **Maintenance**. Choose **Select** to display the **Empty PC/CC Reservoir** window.

2 Select the appropriate **e** 601 module and deselect all other modules. Selected modules are highlighted in white.

3 Choose **Execute**. The PC/CC reservoirs are emptied.

■

► To perform Sipper Air Purge

1 Select **(24) Sipper Air Purge** from the **Maintenance** Items list on **Utility** > **Maintenance**. Choose **Select** to display the **Sipper Air Purge** window.

2 Select the appropriate **e** 601 module and deselect all other modules. Selected modules are highlighted in white.

3 Enter 10 in the Cycles text box and choose **Execute** to perform the Sipper Air Purge.

4 Remove the ProCell and CleanCell reservoir cups.

■

As needed

► To perform daily and weekly maintenance items and finish Power OFF

1 Perform all Daily and Weekly maintenance items excluding Reagent Prime and Finalization.

👁 For more information, see:
Daily maintenance on page C-118
Weekly maintenance on page C-121

2 Choose **Shut Down** (global button) to display the **Shut Down** window.

3 Select the **Shut Down** option and choose **Execute** to confirm the shutdown.

4 Wait until the computer power supply turns off. Then, switch off the power switch of the printer and monitor.

CAUTION! Damage to the control unit or data loss. Before switch-off of the analyzer, make sure the monitor indication has changed from shutdown to a state where nothing is displayed.

5 Switch off the operation power switch on the left side face of the rack sampler unit.

6 Turn off the water supply.

■

Power ON procedures (after Extended Power OFF)

Power ON 1 The procedures below correspond to *Power OFF 1*, an extended Power OFF Procedure applied if the instrument will not be in use for 1 to 2 days (for example, a weekend).

The maintenance items listed in this procedure can be programmed as a maintenance pipe.

👁 See *Recommended maintenance pipes* on page C-32.

► To start the system

1 Switch on the water supply of the system.

2 Switch on the operation power switch, located on the left side of the rack sampler unit.

The analyzer starts the initialization routine (time for **c** 501, **e** 601, and control unit approximately 12 min).

3 Switch on each power switch of the computer, printer, and monitor. While the analyzer is performing initialization the **Logon** screen is displayed.

4 Enter your Operator ID logon and password to log on.

5 Choose **OK** to gain access to the software and begin operation. When initialization is completed, the analyzer goes into standby.

6 Perform the maintenance items listed below in the specified order to prepare the System for routine operation.

■

► To prepare the system for routine operation

1 Select **(37) System Air Purge (E Module)** from the **Maintenance** Items list on **Utility** > **Maintenance**. Choose **Select** to display the **System Air Purge (E Module)** window.

2 Select the **Ch1,2** option and enter 5 in the **Cycles** text box and choose **Execute** to perform this maintenance item 5 times.

3 Select **(8) Reagent Prime** from the **Maintenance** Items list on **Utility** > **Maintenance**. Choose **Select** to display the **Reagent Prime** window.

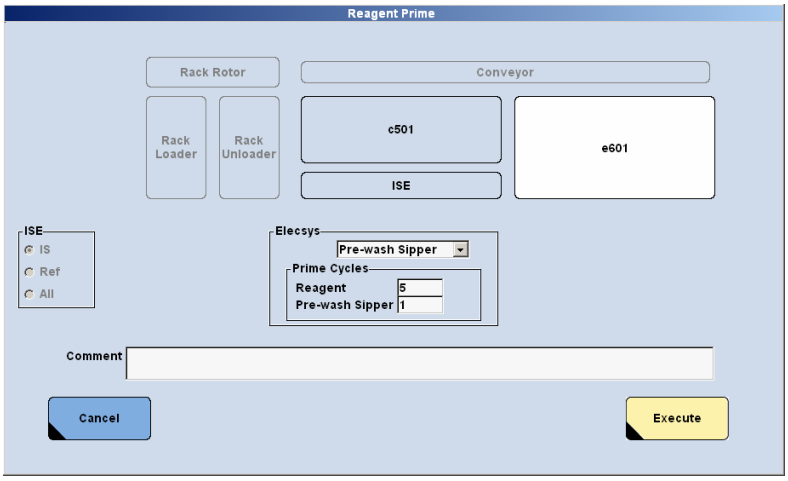


Figure C-63 Reagent Prime window

4 In the **Elecsys** area select **Pre-wash Sipper** from the **e** 601 list box. In the **Prime Cycles** area enter 5 for the **Pre-wash Sipper**

5 Choose **Execute** to start reagent priming.

6 Select **(25) MC Preparation** from the **Maintenance** Items list on **Utility** > **Maintenance**. Choose **Select** to display the **MC Preparation** window.

7 Select the **Ch1,2** option and enter 5 in the **Cycles** text box and choose **Execute** to initiate the MC preparation.

The system is now ready for routine operation.

■

Power ON 2 The procedures below correspond to *Power OFF 2*, an extended Power OFF Procedure applied if the instrument will not be used for 3 to 7 days.

The maintenance items listed in this procedure can be programmed as a maintenance pipe.

See *Recommended maintenance pipes* on page C-32.

► To reload consumables and start the system

1. Return the removed **cobas e** packs to the reagent disk prior to power ON.
2. Discard the ProbeWash, ProCell, CleanCell and PreClean bottles filled with deionized water. Place new ProbeWash, ProCell, CleanCell and PreClean bottles.

 See *Reagent reloading (e 601)* on page B-128.
3. Refill magazine lifter and place new ProCell and CleanCell reservoir cups on the instrument.
4. Switch on the water supply of the system.
5. Switch on the operation power switch, located on the left side of the rack sampler unit.

 The analyzer starts the initialization routine. While the analyzer is performing initialization (time for **c** 501, **e** 601, and control unit approximately 12 min), the **Logon** screen is displayed.
6. Enter your Operator ID logon and password to log on.
7. Choose **OK** to gain access to the software and begin operation. When initialization is completed, the analyzer goes into standby.

Update all system consumables by pressing the corresponding indicator lamps.

8. Perform the maintenance items listed below in the specified order to prepare the System for routine operation.

■

► To prepare the system for routine operation

1 Select **(37) System Air Purge (E Module)** from the **Maintenance** Items list on **Utility** > **Maintenance**. Choose **Select** to display the **System Air Purge** (E Module) window.

2 Select the **Ch1,2** option and enter 5 in the **Cycles** text box and choose **Execute** to perform this maintenance item 5 times.

3 Select **(8) Reagent Prime** from the **Maintenance** Items list on **Utility** > **Maintenance**. Choose **Select** to display the **Reagent Prime** window.

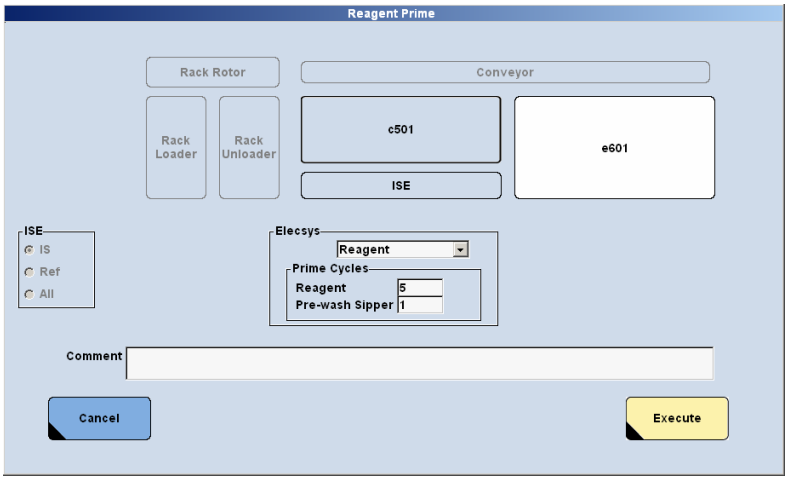


Figure C-64 Reagent Prime window

4 Deselect the **c** 501 module and select the **e** 601 module.

5 In the **Elecsys** area select **Reagent** from the **e** 601 list box. In the **Prime Cycles** area enter 5 for the Reagent.

6 Choose **Execute** to start reagent priming.

7 Select **(25) MC Preparation** from the **Maintenance** Items list on **Utility** > **Maintenance**. Choose **Select** to display the **MC Preparation** window.

8 Select the **Ch1,2** option and enter 30 in the **Cycles** text box to perform MC preparation 30 times on each channel. Choose **Execute** to initiate the MC preparation.

9 Select **(8) Reagent Prime** from the **Maintenance** Items list on **Utility** > **Maintenance**. Choose **Select** to display the **Reagent Prime** window.

10 In the **Elecsys** area select **Pre-wash Sipper** from the **e** 601 list box. In the **Prime Cycles** area enter 5 for the Pre-wash Sipper.

11 Choose **Execute** to start reagent priming.

The system is now ready for routine operation.

■

As needed

Troubleshooting D

19 Data alarms D-3
20 Troubleshooting D-65

Data alarms

This chapter contains the data alarms generated by the **cobas** 6000 system. In addition to a description of the cause of each alarm and remedy, the analytical module of origin and automatic rerun conditions are described here.

In this chapter *Chapter* 19

Introduction D-7
Data alarm list D-10
Data alarms c 501 (ISE) D-12
- ADC.E D-12
- Calc.? D-13
- Cal.E (Sample flag) D-13
- ClcT.E D-13
- CmpT.? D-14
- CmpT.E D-14
- Edited D-14
- >Index D-15
- >I.xxx D-15
- ISE.E D-16
- ISE.N D-16
- <Mix D-17
- Mix.E D-17
- Over.E D-17
- Reag.S D-17
- >Rept / <Rept D-18
- Samp.S D-18
- Samp.C D-18
- < >Test D-19
- >Test / <Test D-19

Data alarms c 501 (P) D-20
- >Abs D-21
- ADC.E D-22
- Calc.? D-22
- ClcT.E D-22
- Cal.E D-23
- CmpT.? D-23

CmpT.E D-23
>Cuvet D-24
Det.S D-25
Edited D-25
>Index D-25
>I.xxx D-26
>Kin D-26
>Lin D-27
Mix.E D-27
<Mix D-27
Over.E D-28
>Proz D-28
>React D-29
ReagEx D-29
>Rept / <Rept D-29
Samp.? D-30
Samp.C D-30
Samp.O D-30
Samp.S D-31
>Test / <Test D-31
Data alarms e 601 module D-32
>AB D-32
AB.E D-32
ADC.E D-33
Calc.? D-33
Cal.E (Sample flag) D-33
CarOvr D-34
Cell.T D-34
Clot.E D-34
>Curr D-35
Curr.E D-35
Edited D-35
Inc.T D-36
Over.E D-36
ReagEx D-36
Reag.F D-36
Reag.H D-37
Reag.T D-37
Reag.S D-37
>Rept / <Rept D-38
Samp.B D-38
Samp.C D-38
Samp.H D-39
Samp.O D-39
Samp.S D-39
<SigL D-40
SLLD.E D-40
SLLD.N D-40
SysR.S D-41
SysR.T D-41

>Test / <Test D-41
WB.S D-42
WB.T D-42
Data alarms for calibrations D-43
Cal.E D-44
Cond.E D-44
Diff.E D-45
Dup.E D-45
Dupl. D-46
IStd.E D-46
Mono.E D-47
Prep.E D-47
Rsp1.E D-48
Rsp2.E D-48
S1A.E D-48
SD.E D-49
Sens.E D-49
>Sig D-50
<Sig D-50
Sig.E D-50
Slop.E D-51
Std.E D-52
c 501 (ISE) D-52
c 501 (P) D-53
Sys.E D-54
Data alarms for controls D-55
Q3SD D-56
Q2.5SD D-57
R4SD D-57
S2-2Sa D-58
S2-2Sw D-58
S4-1Sa D-58
S4-1Sw D-59
S10Xa D-59
S10Xw D-59
Data problems without alarm D-60
Drift of result data D-60
Erroneous operation D-60
Poor reproducibility D-61
Result data at high level D-61
Result data at low level D-61
Trouble attributed to characteristics of reagent D-62
Trouble for each test D-62
Trouble on each analytical module D-62
Trouble on each channel in same module D-62
Rerun list D-63

Table of contents

Introduction

If any abnormality occurs while the system is switched on, the system notifies the operator of the potential problem by issuing an alarm. These alarms comprise data alarms (referring to irregular measuring results or conditions) and instrument alarms (referring to irregular system conditions). Alarms are classified into five levels:

Alarm levels

Data alarm	This alarm is attached to the results of calibrations or to measurement results of QC or patient samples. If a data alarm occurs at calibration or QC sample measurement and if it will affect subsequent measurements, an instrument alarm of the warning level occurs at the same time. The analyzer does not stop operation.
Warning	This alarm is generated by data alarms or troubles on the instrument. If this alarm occurs during operation, the analyzer does not stop operation. The operator must judge whether to continue or interrupt measurement.
Sampling stop	This alarm concerns troubles on the instrument. For the pipetted sample, measurement is continued.
Stop	This alarm concerns troubles on the instrument. The analyzer stops operation within one cycle (6 seconds). For the sample under measurement, no result data are obtained and the measurement must be repeated.
Emergency stop	This alarm concerns troubles on the instrument. The analyzer immediately stops operation. For the sample under measurement, no result data are obtained and the measurement must be repeated.

Alarm indication

Data alarms are indicated on the **Workplace** > **Data Review** screen, on the **Test Review** window (**Workplace** > **Data Review** > **Test Review**), and on printed reports. If a data alarm occurs, an abbreviation (also referred to as flag) is attached to the measurement result. These flags are strings of three to six characters, which are all explained in this chapter.

Instrument alarms are indicated by the **Alarm** button (global button) on the **System Overview** screen as well as by an audible alarm. If an alarm occurs, the **Alarm** button lights up. Its color indicates the alarm level: Yellow indicates warning level, red indicates sampling stop or emergency stop.

In case of an alarm choose the **Alarm** button to open the **Alarm** window. This window provides an alarm list and descriptions and remedies for each listed alarm.

Data alarm priority

The system displays one data flag for each result in the **Alarm** column. If more than one data flag is associated with a test result, the system displays the alarm depending on the data alarm priority.

The figure below shows the data alarm priority of the **cobas** 6000 analyzer series:

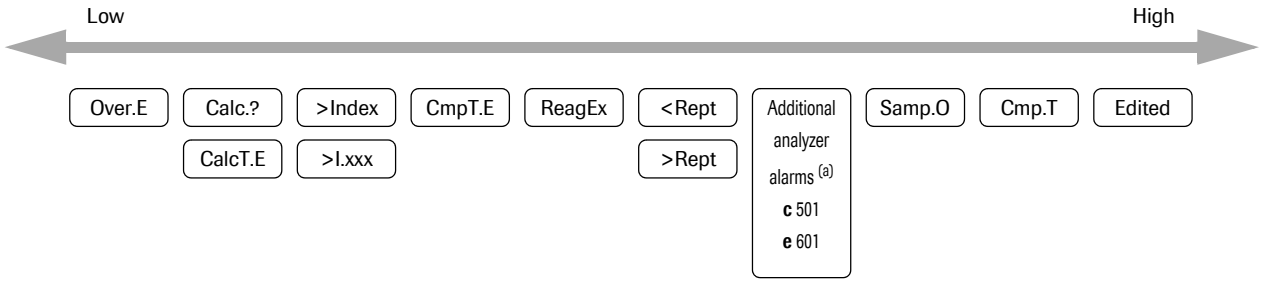


Figure D-1 Data alarm priority of the **cobas** 6000 analyzer series

(a) See data alarm priority of the **c** 501 module and of the **e** 601 module.

The figure below shows the data alarm priority of the **c** 501 module:

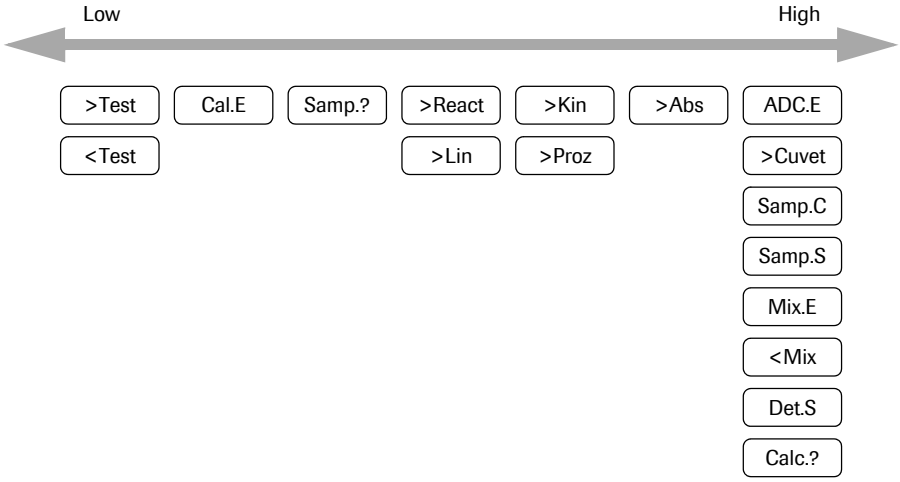


Figure D-2 Data alarm priority of the **c** 501 module

The figure below shows the data alarm priority of the **e** 601 module:

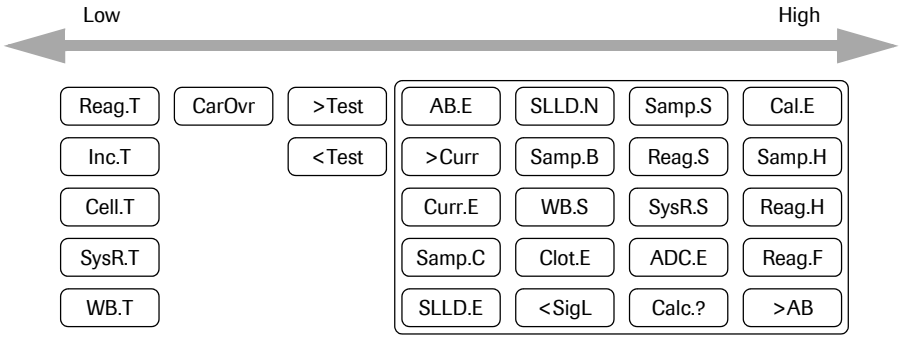


Figure D-3 Data alarm priority of the **e** 601 module

Automatic rerun

If a data alarm occurs on a test for which automatic rerun is selected (check box on **Utility** > **Application** > **Range**), a rerun is automatically requested. For execution of the automatic rerun during measurement, however, automatic rerun needs to be activated on the **Start Conditions** screen as well.

For more information, see *Rerun list* on page D-63.

For QC and patient samples, a data alarm consists of an alarm message and a result message. The result messages are specific to the **cobas** 6000 tests.

For tables and lists provide an overview of the data alarms, see:
Data alarm list on page D-10
Data alarms c 501 (ISE) on page D-12
Data alarms c 501 (P) on page D-20
Data alarms e 601 module on page D-32
Data alarms for controls on page D-55
Data problems without alarm on page D-60
Rerun list on page D-63

Data alarm list

The following table displays the data alarms applicable to ISE tests, **c** 501 tests, **e** 601 tests, and their presentation (flag) on screens and reports.

Flag	Alarm	c 501 (ISE)	c 501 (P)	e 601
>AB	AB level range over (Assay Buffer=ProCell)	–	–	✓
AB.E	AB level check error	–	–	✓
>Abs	ABS over	–	✓	–
ADC.E	ADC abnormal	✓	✓	✓
Cal.E (Sample flag)	Calibration result abnormal (Sample flag)	✓	✓	✓
Calc.?	Calculation not possible	✓	✓	✓
CarOvr	Potential microbeads carryover	–	–	✓
Cell.T	Measuring cell temperature out of range	–	–	✓
ClcT.E	Calculated test error	✓	✓	–
Clot.E	Clot pressure abnormal	–	–	✓
CmpT.?	Unable to calculate compensated test	✓	✓	–
CmpT.E	Data error in compensated test	✓	✓	–
>Curr	Current range over	–	–	✓
Curr.E	Current range check error	–	–	✓
>Cuvet	Cell blank abnormal	–	✓	–
Det.S	Carry over detergent short	–	✓	–
Edited	Edited test	✓	✓	✓
Inc.T	Incubator temperature	–	–	✓
>Index	Serum index check	✓	✓	–
>I.xxx	Serum index check	✓	✓	–
ISE.E	ISE voltage level error	✓	–	–
ISE.N	ISE noise error	✓	–	–
>Kin	Prozone error 2 / Kinetic unstable	–	✓	–
>Lin	Linearity abnormal	–	✓	–
Mix.E	Ultrasonic mixing error	✓	✓	–
<Mix	Mixing power low level	✓	✓	–
Over.E	Overflow	✓	✓	✓
>Proz	Prozone error 1	–	✓	–
>React	Reaction limit over (substrate depletion)	–	✓	–
ReagEx	Reagent expired	–	✓	✓
Reag.F	Reagent film detected	–	–	✓
Reag.H	Reagent hovering	–	–	✓
Reag.S	Reagent short	✓	–	✓
Reag.T	Reagent disk temperature	–	–	✓
>Rept / <Rept	Repeat limit over (upper / lower)	✓	✓	✓

Table D-1 Data alarm list (Sheet 1 of 2)

Flag	Alarm	c 501 (ISE)	c 501 (P)	e 601
Samp.?	ABS maximum over (non-lin curve)	–	✓	–
Samp.B	Sample air bubble	–	–	✓
Samp.C	Sample clot	✓	✓	✓
Samp.H	Sample hovering	–	–	✓
Samp.O	Potential carryover during processing of the rerun measurement	–	✓	✓
Samp.S	Sample short	✓	✓	✓
<SigL	Low signal level	–	–	✓
SLLD.E	Sample LLD abnormal	–	–	✓
SLLD.N	Sample LLD noise	–	–	✓
SysR.S	Auxiliary reagent short	–	–	✓
SysR.T	Auxiliary reagent temperature	–	–	✓
< >Test	Sample range over	✓	–	–
>Test / <Test	Upper/Lower technical Limit	✓	✓	✓
WB.S	Washing buffer short (PreClean)	–	–	✓
WB.T	Washing buffer temperature (PreClean)	–	–	✓

Table D-1 Data alarm list (Sheet 2 of 2)

Data alarms c 501 (ISE)

In this section you find the data alarms of the **c** 501 (ISE) module.

By clicking on this symbol ✓ you will be linked to the corresponding data alarm.

Flag	c 501 (ISE)	Flag	c 501 (ISE)	Flag	c 501 (ISE)
ADC.E	✓	IStd.E	✓	S2-2Sa	✓
Cal.E	✓	Mix.E	✓	S2-2Sw	✓
Cal.E (Sample flag)	✓	<Mix	✓	S4-1Sa	✓
Calc.?	✓	Over.E	✓	S4-1Sw	✓
ClcT.E	✓	Prep.E	✓	S10Xa	✓
CmpT.?	✓	Q2.5SD	✓	S10Xw	✓
CmpT.E	✓	Q3SD	✓	Samp.C	✓
Cond.E	✓	>Rept	✓	Samp.S	✓
Edited	✓	<Rept	✓	Slop.E	✓
>I.xxx	✓	R4SD	✓	Std.E	✓
>Index	✓	Reag.S	✓	< >Test	✓
ISE.E	✓	Rsp1.E	✓	>Test	✓
ISE.N	✓	Rsp2.E	✓	<Test	✓

Table D-2 Data alarm list **c** 501(ISE)

ADC.E

Alarm ADC abnormal

Description The analog/digital converter does not work normally.

Cause Numerical conversion of the electromotive force is abnormal.

Remedy
1. If other instrument alarm exists, correct those alarms and resume operation.
2. Choose **Utility** > **Maintenance** and perform maintenance item (1) Reset. If the alarm recurs call Roche service representative.

Calc.?

Alarm Calculation not possible

Description The denominator becomes zero in calculation.

1. During calculation the denominator became zero.
2. An overflow occurred in logarithmic or exponential calculation.
3. Result was left blank.

Cause Internal calculation error has occurred.

Remedy
1. Check the test that is flagged with an error message in the calculation. Dilute the sample and rerun the sample.
2. Check the calibration type list box on **Utility** > **Application** > **Calib**.
3. Resume operation. If alarm recurs, call Roche service representative.

Cal.E (Sample flag)

Alarm Calibration result abnormal (Sample flag)

Description No calibration data or previous calibration data used.

Cal.E appears on each QC and patient sample for the affected test until the problem is resolved.

Cause No valid calibration stored in the system or the last calibration has failed.

Remedy
1. Correct the condition causing the alarm that occurred during the last calibration attempt.
2. Recalibrate.

ClcT.E

Alarm Calculated test error

Description Calculation error has occurred.

Cause A data alarm has occurred for a test needed in the calculation. This is **not** valid for the following errors and alarms:

- Calculation not possible (Calc.?)

Remedy
1. Correct the data alarm of the test to be used on the calculation.
2. Recalibrate.

CmpT.?

Alarm Unable to calculate compensated test

Description During test-to-test compensation calculation, the denominator became zero. Blank space is left in the report.

Cause
1. The test used for test-to-test compensation has not been measured yet.
2. Any test used for test-to-test compensation has data alarm calculation not possible (Calc.?) or test-to-test compensation error (CmpT.E).
3. Any test used in the compensation formula has a data alarm that leaves the result blank (for example, Samp.S, Reag.S).

Remedy Correct the data alarm of the test to be used for compensation. Rerun the sample.

CmpT.E

Alarm Data error in compensated test

Description
1. In test-to-test compensation calculation, a data alarm other than those shown below is indicated for the compensation test data.
2. Calculation not possible, test-to-test compensation disabled, overflow, random error, systematic error, QC error and outside of expected value.

Cause The test to be used for compensation has a data alarm.

Remedy Correct the data alarm on the test to be used for compensation. Rerun the sample.

Edited

Alarm Edited test

Description An edited first result or replaced rerun result is marked with an *Edited* alarm on the **Data Review** screen. This also prints on the patient report.

Cause The result data has been edited.

Remedy Check the result of measurement.

>Index

Alarm Serum index check

Description The L (lipemic), H (hemolytic), or I (icteric) result is greater than the specified value (**Utility** > **Application** > **Range**).

The serum index check is performed after all test results are generated. If a data alarm is already attached to the result, no serum index check will be performed.

Cause A highly lipemic, hemolytic, or icteric sample has been measured.

Remedy Check the result of measurement.

>I.xxx

Alarm Serum index check

Description The L (lipemic), H (hemolytic), or I (icteric) result is greater than the specified value (**Utility** > **Application** > **Range**).

Possible >I.xxx alarms are:

- >I.L
- >I.H
- >I.I
- >I.LH
- >I.LI
- >I.HI
- >I.LHI

The combination of L, H, I indicates which serum index value is exceeded. For example, the data alarm >I.LH indicates, that the serum index values of L and H are exceeded.

The serum index check is performed after all test results are generated. If a data alarm is already attached to the result, no serum index check will be performed.

Cause A highly lipemic, hemolytic, or icteric sample has been measured.

Remedy Check the result of measurement.

ISE.E

Alarm ISE voltage level error

Description During measurement of internal reference, the EMF was not within the following ranges (ISE IS):

Na^+	-90.0 to -10 mV
K^+	-90.0 to -10 mV
Cl^-	80.0 to 160 mV

Cause
- The reference electrode is deteriorated.
- Insulation is poor due to liquid leakage from the reference electrode mounting section.
- ISE IS is deteriorated.

Remedy
1. Set the reagent and perform maintenance item (8) Reagent Prime for the ISE unit.
2. Replace the electrode and perform maintenance item (8) Reagent Prime for the ISE unit.
3. Make sure that the O-ring is attached to the electrode joint and then perform maintenance item (8) Reagent Prime for the ISE unit.
4. Set the internal standard solution properly and perform maintenance item (8) Reagent Prime for the ISE unit.
5. Check that the electrode cords are correctly connected.

ISE.N

Alarm ISE noise error

Description In ISE measurement, the fluctuation in electromotive force exceeds the following value:

Na^+	0.7 mV
K^+	1.0 mV
Cl^-	0.8 mV

Cause
- Entry of air bubbles for lack of reagent
- Entry of air bubbles due to improper attachment of electrode
- Entry of air bubbles through sipper tube
- Poor insulation of waste solution block
- Poor insulation due to liquid leakage from sipper pipetter

Remedy

1. Check for sufficient reagent volume, make sure the tubing sits correctly in the ISE Ref. bottle, and perform maintenance item (8) Reagent Prime for the ISE unit (All).
2. Make sure that the O-ring is attached to the electrode joint and perform maintenance item (8) Reagent Prime for the ISE unit (All).
3. Replace the sipper tube and perform maintenance item (8) Reagent Prime for the ISE unit (All).
4. Eliminate deposits.
5. Carry out cleaning, checkup, and maintenance of the sipper syringe.

<Mix

Alarm Mixing power low level

For more information, see <*Mix* on page D-27.

Mix.E

Alarm Ultrasonic mixing error

For more information, see *Mix.E* on page D-27.

Over.E

Alarm Overflow

Description Display is not possible because the output figure exceeds 6 digits

Cause The data is obtained in more than six digits including a negative sign and decimal places.

Remedy

1. Minimize the difference in concentration between the sample and calibrator.
2. Obtain the result data with six characters including negative sign and decimal places.

Reag.S

Alarm Reagent short

Description There is insufficient ISE reagent volume when alarm is associated with sodium, potassium and chloride values.

Cause There is not enough reagent in the reagent bottle.

Remedy

1. Verify adequate reagent volumes. Replace low reagent, as necessary. Prime new reagent and recalibrate.
2. If adequate reagent volumes are present, verify volumes on the **Reagent** screen. Rerun the sample.
3. Resume operation. If alarm recurs, call Roche service representative.

>Rept / <Rept

Alarm Repeat limit over (upper / lower)

Description The result falls outside the repeat limit range programmed on **Utility** > **Application** > **Range**.

Cause The sample concentration is higher or lower (>Rept / <Rept) than the set value.

Remedy This alarm can be activated on **Utility** > **System** (**Page 1/4**) > **Alarm**. If activated, the system can also be programmed to automatically repeat this test with normal sample volume.

Samp.S

Alarm Sample short

Description The liquid level cannot be detected in the sample container.

Cause The sample volume is insufficient in the sample container.

Remedy
1. Add sample and rerun.
2. Resume operation. If alarm recurs, call Roche service representative.

Samp.C

Alarm Sample clot

Description The specified volume of sample is not aspirated.

Cause A clot is detected.

Remedy
1. Perform maintenance item (12) Sample Probe Wash.
2. Check if there are clots in the sample.
3. If necessary remove the clots from the sample and rerun.
4. If alarm recurs, call Roche service representative.

< >Test

Alarm Sample range over

Description If the data is out of the following ranges, Sample range over is issued:

Na^+	10-250 mmol/L
K^+	1-100 mmol/L
Cl^-	10-250 mmol/L

Cause
- The electrode is deteriorated.
- The flow path is contaminated.
- Sample concentration is too high or too low.

Remedy
1. Are controls in range?

 If Yes, go to 2.

 If No, go to 3.
2. Continue with routine analysis. Continue with step 3 at the end of the day.
3. Replace the appropriate cartridge.



Replacing ISE cartridges must only be done by specially trained operators.

For more information, refer to the separate maintenance manual *Interlock function cobas* **c** 501 *with ISE.*

4. Resume operation.

 If alarm recurs, call Roche service representative.

>Test / <Test

Alarm Upper/Lower technical Limit

Description The sample concentration is outside the technical range entered on **Utility** > **Application** > **Range**.
- Over the technical limit: Value is greater than the upper limit (>Test).
- Under the technical limit: Value is less than the lower limit (<Test).

Cause Sample concentration is too high or too low.

Remedy
1. Manually dilute and rerun the diluted sample until the measured concentration is within the specified range. Be sure to calculate the original concentration from the measured value, using the correct dilution factor.

 In case of urine samples with a >Test alarm, a manual rerun can be performed with decreased volume (6.5 µL instead of normal volume).
2. Perform maintenance item (12) Sample Probe Wash.
3. Clean the outside of the sample probe manually.

 If alarm recurs, call Roche service representative.

Data alarms c 501 (P)

In this section you find the data alarms of the **c** 501 (P) module.

By clicking on this symbol ✓ you will be linked to the corresponding data alarm.

Flag	c 501(P)	Flag	c 501(P)	Flag	c 501(P)
>Abs	✓	>Lin	✓	S2-2Sw	✓
ADC.E	✓	<Mix	✓	S4-1Sa	✓
>Cuvet	✓	Mix.E	✓	S4-1Sw	✓
Cal.E (Sample flag)	✓	Over.E	✓	S10Xa	✓
Calc.?	✓	>Proz	✓	S10Xw	✓
ClcT.E	✓	Q2.5SD	✓	Samp.?	✓
CmpT.?	✓	Q3SD	✓	Samp.C	✓
CmpT.E	✓	>React	✓	Samp.O	✓
Det.S	✓	>Rept	✓	Samp.S	✓
Dup.E	✓	<Rept	✓	SD.E	✓
Edited	✓	R4SD	✓	Sens.E	✓
>Index	✓	ReagEx	✓	Std.E	✓
>I.xxx	✓	S1A.E	✓	>Test	✓
>Kin	✓	S2-2Sa	✓	<Test	✓

Table D-3 Data alarm list **c** 501(P)

>Abs

Alarm ABS over

Description The absorbance value to be used for calculation after cell blank correction exceeded 33000.

Cause
- The sample concentration is too high or the sample is lipemic.
- The reagent has not been stored or handled properly.
- Obstructions are in the optical path of the photometer.

Remedy
- If only one sample is affected: Check whether the sample is grossly lipemic or has an extremely high value. Follow your laboratory protocol for this situation.
- If only one application is affected: Check reagent storage and handling for that test.
- If all samples are affected:
 - Remove any obstructions in the optical path of the photometer. Make sure the lamp is on.
 - Choose **Utility** > **Maintenance** and perform maintenance item (5) Incubation Water Exchange
 - Clean the incubator bath if it is contaminated.
 For further instructions, see:
 Replacing reaction cells on page C-86
 Cleaning the incubator bath on page C-88
 - Choose **Utility** > **Maintenance** and perform maintenance item (3) Photometer Check.
 - Check the Photometer Check results on the printout (Abs < 14000).
 - Replace the photometer lamp, if necessary.
 - Resume operation. If alarm recurs, call Roche service representative.
- If all samples are affected intermittently:
 - If any reaction cell is scratched, replace the cell.
 For further instructions, see:
 Replacing reaction cells on page C-86
 Cleaning the incubator bath on page C-88

ADC.E

Alarm ADC abnormal

Description The analog-digital converter does not work normally.

Cause
1. Numerical conversion is abnormal.
2. The cell count is abnormal.

Remedy
1. If other instrument alarms exist, correct those alarms and resume operation.
2. Choose **Utility** > **Maintenance** and perform maintenance item (1) Reset.
3. If the alarm recurs, remove the reaction disk and check for water droplets or dust on sensors. Clean if necessary.
4. If the alarm recurs call Roche service representative.

Calc.?

Alarm Calculation not possible

Description The denominator becomes zero in calculation.
- During calculation the denominator became zero.
- An overflow occurred in logarithmic or exponential calculation.
- Result was left blank.

Cause Internal calculation error has occurred.

Remedy
1. Check the test that is flagged with an error message in the calculation.
2. Rerun with a suitable dilution ratio (**Workplace** > **Test Selection** > **S.Vol./D.Ratio**).
3. Check the calibration type list box on **Utility** > **Application** > **Calib**.
4. Resume operation. If alarm recurs, call Roche service representative.

ClcT.E

Alarm Calculated test error

Description Calculation error has occurred.

Cause A data alarm has occurred for the test needed in the calculation. This is not valid for the following data alarms:
- Calculation not possible (Calc.?)
- Reagent expired date (ReagEx)

Remedy
1. Correct the data alarm of the test to be used on the calculation.
2. Recalibrate.

Cal.E

Alarm Calibration result abnormal (Sample flag)

Description No calibration data or previous calibration data used in case of a failed calibration.

Cal.E appears on each QC and patient sample for the affected test until the problem is resolved.

Cause No valid calibration stored in the system or the attempted calibration has failed.

Remedy
1. Correct the condition causing the alarm that occurred during the failed calibration.
2. Recalibrate.

CmpT.?

Alarm Unable to calculate compensated test

Description During test-to-test compensation calculation, the denominator became zero. Blank space is left in the report.

Cause
1. The test used for test-to-test compensation has not been measured yet.
2. Any test used for test-to-test compensation has data alarm calculation not possible (Calc.?) or test-to-test compensation error (CmpT.E).
3. Any test used in the compensation formula has a data alarm that leaves the result blank (for example, Samp.S, Reag.S).

Remedy Correct the data alarm of the test to be used for compensation. Rerun the sample.

CmpT.E

Alarm Compensation Error Between Tests

Description
1. In test-to-test compensation calculation, a data alarm for the compensation test data is indicated.
2. Calculation not possible, test-to-test compensation disabled, overflow, random error, systematic error, QC error and outside of expected value.

Cause The test to be used for compensation has a data alarm.

Remedy Correct the data alarm on the test to be used for compensation. Rerun the sample.

>Cuvet

Alarm Cell blank abnormal

Description For a diluted test the cell blank value of the second reaction cell exceeds the reference by more than 0.1 Abs. The reference is the stored value from the **(4) Cell Blank Measurement**.

If a reaction cell fails the cell blank measurement, the system excludes it from any measurements.

For diluted tests however, the system uses two reaction cells:

- 1st cell: Contains sample and diluent.
- 2nd cell: Used for discharging diluted sample from the 1st cell, adding reagent, and performing measurement.

The >*Cuvet* alarm indicates a failed cell blank measurement for the 2nd cell.

For more information about cell blank measurement, see:
Cell rinse unit on page A-80
Main steps of photometric analysis on page A-83
To perform a cell blank measurement on page C-78
To view the cell blank measurement results on page C-79

Cause Reaction cells are contaminated or damaged.

Remedy

1. Check that the reaction cell is not contaminated or cracked.
2. Choose **Utility** > **Maintenance** and perform maintenance item **(7) Wash Reaction Parts**.
3. Ensure that there is no excessive foaming or particles in the incubator bath.

 If you notice excessive foaming or particles, perform maintenance item **(5) Incubation Water Exchange**.
4. Wipe the outside of the reaction cells with a gauze pad moistened with incubator bath water.
5. Resume operation. If alarm recurs, ensure there is adequate rinse water and cell blank water from the rinse mechanism. The cells must be completely filled.
6. Choose **Utility** > **Maintenance** and perform maintenance item **(5) Incubation Water Exchange**.
7. Resume operation. If alarm recurs, choose **Utility** > **Maintenance** and perform maintenance item **(4) Cell Blank Measurement**.

 If an **Abnormal Cell List** is displayed on the **Cell Blank Measurement** report, the cell blank failed. For the cells listed in the **Abnormal Cell List**, the cell blank value differs more than ± 1000 (± 0.1 Abs) compared to cell no. 1. These cells need to be inspected (or replaced) and the **(4) Cell Blank Measurement** must be performed again.

 For further instructions, see:
 To perform a cell blank measurement on page C-78
 Replacing reaction cells on page C-86
8. Resume operation. If alarm recurs, call Roche service representative.

Det.S

Alarm Carry over detergent short

Description If a special wash for the reagent probe is defined, the reagent probe immerses into the specified detergent cassette. This alarm occurs, if the test is carried out even though the detergent volume is insufficient.

Cause The residual volume of the special wash detergent is insufficient.

Remedy
1. Load a new detergent cassette.
2. Check the results of the measurement and rerun the sample if necessary.

Edited

Alarm Edited test

Description An edited first result or replaced rerun result is marked with an *Edited* alarm on the **Data Review** screen. This also prints on the patient report.

Cause The result data has been edited.

Remedy Check the result of measurement.

>Index

Alarm Serum index check

Description The L (lipemic), H (hemolytic), or I (icteric) result is greater than the specified value (**Utility** > **Application** > **Range**).

The serum index check is performed after all test results are generated. If a data alarm is already attached to the result, no serum index check will be performed.

Cause A highly lipemic, hemolytic, or icteric sample has been measured.

Remedy Check the result of measurement.

>I.xxx

Alarm Serum index check

Description The L (lipemic), H (hemolytic), or I (icteric) result is greater than the specified value (**Utility** > **Application** > **Range**).

Possible >I.xxx alarms are:

- >I.L
- >I.H
- >I.I
- >I.LH
- >I.LI
- >I.HI
- >I.LHI

The combination of L, H, I indicates which serum index value is exceeded. For example, the data alarm >I.LH indicates, that the serum index values of L and H are exceeded.

The serum index check is performed after all test results are generated. If a data alarm is already attached to the result, no serum index check will be performed.

Cause A highly lipemic, hemolytic, or icteric sample has been measured.

Remedy Check the result of measurement.

>Kin

Alarm Prozone error 2 / Kinetic unstable

Description The prozone check value exceeds the specified limit value. (Reaction rate method)

Cause
- The sample concentration is too high. The monotone kinetic check value exceeds the specified limit for other tests.
- The limit value is not set properly.

Remedy
1. Rerun with **Decrease** sample concentration or a suitable dilution ratio (**Workplace** > **Test Selection** > **S.Vol./D.Ratio**).
2. To avoid check, set [0] [0] [0] [0] [0] [Inside] [0] [0] for Prozone Limit (on **Utility** > **Application** > **Analyze**).

>Lin

Alarm Linearity abnormal

Description In rate assay, the reaction linearity exceeds the specified limit value.

Cause
- The photometer lamp is deteriorated.
- The linearity check value is not set properly.
- The sample is extremely lipemic.
- The ultrasonic mixers are defective.
- Debris are in the incubator bath.

Remedy
1. Check the photometer lamp.
2. Rerun with a suitable dilution ratio (**Workplace** > **Test Selection** > **S.Vol./D.Ratio**).
3. Choose **Utility** > **Application** > **Analyze** to check the Linearity Limit.
4. Choose **Utility** > **Maintenance** > **Check** (on **Maintenance Type** list) and perform maintenance check (7) Cuvette Mixing to check the ultrasonic mixing mechanisms.
5. Ensure the incubator bath is free of debris. Clean the incubator bath, if necessary.
 See *Cleaning the incubator bath* on page C-88.
6. Resume operation. If alarm recurs, call Roche service representative.

Mix.E

Alarm Ultrasonic mixing error

Description There is no ultrasonic output for mixing.

Cause
- The water level in the incubator bath is too low.
- The water level sensor of the incubator bath is abnormal.

Remedy Supply water to the incubator bath.

<Mix

Alarm Mixing power low level

Description The ultrasonic monitor value is lower than the reference value.

Cause The ultrasonic mixer is deteriorated.

Remedy
1. Clean the surface of the ultrasonic mixers.
 See *Cleaning the ultrasonic mixers* on page C-98.
2. Call Roche service representative.

Over.E

Alarm Overflow

Description Display is not possible because the output figure exceeds 6 digits

Cause
- The K factor has more than six digits due to the use of a wrong calibrator decimal place.
- The data is obtained in more than six digits including a negative sign and decimal places.

Remedy
- Reduce the number of decimal places used for the calibrator 1.
- Obtain the result data with six characters including negative sign and decimal places.

>Proz

Alarm Prozone error 1

Description The prozone check value exceeds the specified limit value. (Antigen readdition method)

Cause
- The sample concentration is too high for immunological test.
- The limit value is not set properly.

Remedy
1. Check the reagent preparation.
2. Rerun with **Decrease** sample concentration or a suitable dilution ratio (**Workplace** > **Test Selection** > **S.Vol./D.Ratio**).
3. Choose **Utility** > **Application** > **Analyze** to check the upper prozone limit.
4. Resume operation. If the alarm recurs, call Roche service representative.

>React

Alarm Reaction limit over (substrate depletion)

Description In a rate assay, the rate of change in main wavelength absorbance exceeds the specified limit value.

Cause
- The sample concentration is too high.
- The reagent has been prepared improperly or deteriorated.
- On **Utility** > **Application** > **Analyze** there is an improper setting in the **Increase/Decrease** box in the **Abs. Limit** line.

Remedy
1. Verify the setting in the **Increase/Decrease** box on **Utility** > **Application** > **Analyze**.
2. Rerun with **Decrease** sample concentration or a suitable dilution ratio (**Workplace** > **Test Selection** > **S.Vol./D.Ratio**).
3. Prepare the reagent newly.

ReagEx

Alarm Reagent expired

Description The alarm indicates that an expired reagent was used; the test result is not guaranteed. The alarm can be inactivated under **Utility** > **System** > **Alarm**.

Cause The system detected an expired reagent on board the analyzer.

Remedy
1. Check the **Reagent Overview** screen for expired reagents.
 For more information, see *Reagent Overview button* on page B-141.
2. Exchange expired reagents.

>Rept / <Rept

Alarm Repeat limit over (upper / lower)

Description The result falls outside the repeat limit range programmed on **Utility** > **Application** > **Range**.

Cause The sample concentration is higher (>Rept) or lower (<Rept) than the set value.

Remedy This alarm can be activated on **Utility** > **System** (**Page 1/4**) > **Alarm**. If activated, the system can also be programmed to automatically repeat this test with normal sample volume.

Samp.?

Alarm ABS maximum over (non-lin curve)

Description The absorbance of a sample is found equal or greater than the theoretical maximum absorbance (for infinite analyte concentration). The result field will be left blank on the report and **Data Review** screen. This blank result is transmitted, together with the alarm code "46" to the Host.

Cause The sample concentration is too high.

Remedy Dilute the sample, if required, and rerun. If automatic rerun is programmed, the determination will be rerun with a decreased sample concentration.

Samp.C

Alarm Sample clot

Description The specified volume of sample is not aspirated.

For more information, see *Samp.C* on page D-18.

Samp.O

Alarm Potential carryover during processing of the rerun measurement

Description If a sample probe wash is defined for a photometric test and this test is requested for a sample that has been already measured, the Samp.O flag is attached to the test result.

For information about defining a sample probe wash for photometric tests, see *Sample probe wash* on page B-302.

Cause Required measurement condition does not correspond to sample probe wash configuration for this test.

Remedy Repeat measurement with a new sample aliquot.

Samp.S

Alarm Sample short

Description The liquid level cannot be detected in the sample container.

For more information, see *Samp.S* on page D-18.

>Test / <Test

Alarm Upper/Lower technical Limit

Description The sample concentration is outside the technical range entered on **Utility** > **Application** > **Range**.

- Over the technical limit: Value is greater than the upper limit (>Test).
- Under the technical limit: Value is less than the lower limit (<Test).

Cause Sample concentration is too high or too low.

Remedy

1. Manually dilute and rerun the diluted sample until the measured concentration is within the specified range. Be sure to calculate the original concentration from the measured value, using the correct dilution factor.
2. Perform maintenance item (12) Sample Probe Wash.
3. Clean the outside of the sample probe manually.

 If alarm recurs, call Roche service representative.

Data alarms e 601 module

In this section you find the data alarms of the **e** 601 module.

By clicking on this symbol ✓ you will be linked to the corresponding data alarm.

Flag	e 601	Flag	e 601	Flag	e 601
>AB	✓	Q3SD	✓	S10Xw	✓
AB.E	✓	>Rept	✓	Samp.B	✓
ADC.E	✓	<Rept	✓	Samp.C	✓
>Curr	✓	R4SD	✓	Samp.H	✓
Cal.E (Sample flag)	✓	ReagEx	✓	Samp.O	✓
Calc.?	✓	Reag.F	✓	Samp.S	✓
CarOvr	✓	Reag.H	✓	Sig.E	✓
Cell.T	✓	Reag.S	✓	SLLD.E	✓
Clot.E	✓	Reag.T	✓	SLLD.N	✓
Curr.E	✓	>Sig	✓	Sys.E	✓
Diff.E	✓	<Sig	✓	SysR.S	✓
Dup.E	✓	<SigL	✓	SysR.T	✓
Edited	✓	S2-2Sa	✓	>Test	✓
Inc.T	✓	S2-2Sw	✓	<Test	✓
Mono.E	✓	S4-1Sa	✓	WB.S	✓
Over.E	✓	S4-1Sw	✓	WB.T	✓
Q2.5SD	✓	S10Xa	✓		

Table D-4 Data alarm list **e** 601

>AB

Alarm AB level range over (Assay Buffer=ProCell)

Description During run preparation, the ProCell signal level is out of range.

Cause ProCell is evaporated or may be contaminated.

Remedy Check for air bubbles in the ProCell reservoir. Replace with a new ProCell bottle.

AB.E

Alarm AB level check error

Description The ProCell level check failed.

Cause ProCell liquid level check failed. The ProCell Volume is inadequate for run preparation.

Remedy Replace the low volume bottle with a new bottle.

ADC.E

Alarm ADC abnormal

Description The analog-digital converter does not work normally.

Cause
- Numerical conversion is abnormal.
- The cell count is abnormal.

Remedy
1. If other instrument alarms exist, correct those alarms and resume operation.
2. Choose **Utility** > **Maintenance** and perform maintenance item (1) Reset.
3. If the alarm recurs, remove the reaction disk and check for water droplets or dust on sensors. Clean if necessary.
4. If the alarm recurs call Roche service representative.

Calc.?

Alarm Calculation not possible

Description The denominator becomes zero in calculation.

Cause Internal calculation error occurred.

Remedy Rerun the sample.

Cal.E (Sample flag)

Alarm Calibration result abnormal (Sample flag)

Description No calibration data or previous calibration data used.

Cal.E appears on each QC and patient sample for the affected test until the problem is resolved.

Cause
- There is no valid calibration stored in the system.
- The attempted calibration has failed.

Remedy
1. Correct the condition causing the alarm that occurred during the latest calibration.
2. Repeat the calibration.
3. Replace with new calibrators and a **cobas e** pack. Repeat the calibration.

CarOvr

Alarm Potential microbeads carryover

Description The signal level of this sample is low.

Cause Microbeads carryover from the previous sample may have occurred.

Remedy Rerun the sample.

Exception: Do not rerun the sample if either qualitative assays are negative or quantitative assays are below the lower limit of the clinical decision.

Cell.T

Alarm Measuring cell temperature out of range

Description Measuring cell temperature is out of range. The system performs an initial check 30 minutes after start-up. The temperature is checked continuously thereafter.

Cause
- The reagent disk cover is open. Radiation of heat does not work normally.
- The room temperature is out of range.

Remedy
1. Verify the temperature of ProCell/CleanCell. Check the fans at the rear part of the module are operating normally and are free of obstructions.
2. Check that room temperature is between 18°C and 32°C (64.4°F and 89.6°F).

Clot.E

Alarm Clot pressure abnormal

Description In checking of the pressure sensor, overflow data is detected.

Cause There are air bubbles in the water flow tube.

Remedy Choose **Utility** > **Maintenance** and perform maintenance item (23) Pipetter Air Purge (10 cycles).

Resume measurement. If the alarm recurs, contact the Roche service representative.

>Curr

Alarm Current range over

Description The measuring cell current is out of range when checked during run preparation.

Cause Abnormal measuring cell condition.

- There are air bubbles in the ProCell reservoir.
- The electrode of the measuring cell is contaminated or deteriorated.

Remedy

1. Check for air bubbles in the ProCell reservoir. Replace with a new ProCell bottle.
2. Choose **Utility** > **Maintenance** and perform maintenance item (27) Liquid Flow Cleaning.

During operation:

1. Choose **Utility** > **Maintenance** and perform maintenance item (25) MC Preparation (10 cycles).
2. Rerun the sample. If alarm recurs immediately, call Roche service representative.

Curr.E

Alarm Current range check error

Description The measuring cell current check failed.

Cause ProCell liquid level check failed. The ProCell Volume is inadequate for run preparation.

Remedy Replace the low volume bottle with a new bottle.

Edited

Alarm Edited test

Description An edited first result or replaced rerun result is marked with an *Edited* alarm on the **Data Review** screen. This also prints on the patient report.

Cause The result data has been edited.

Remedy Check the result of measurement.

Inc.T

Alarm Incubator temperature

Description Incubator temperature is out of range. The system performs an initial check 30 minutes after start-up. The temperature is checked continuously thereafter.

Cause
- Radiation of heat does not work normally.
- The room temperature is out of range

Remedy
1. Check the fans at the back of the module are operating normally and are free of obstructions.
2. Check that room temperature is between 18°C and 32°C (64.4°F and 89.6°F).

Over.E

Alarm Overflow

Description Display is not possible because the output figure exceeds 7 digits

Cause The display of the data result is not possible due to more than 7 digits.

Remedy
- Check the decimal places of the target value of the calibrator 1.
- Repeat the calibration.

ReagEx

Alarm Reagent expired

Description The alarm indicates that an expired reagent was used; the test result is not guaranteed. The alarm can be inactivated under **Utility** > **System** > **Alarm**.

Cause The system detected an expired reagent on board the analyzer.

Remedy
1. Expired reagents are listed on the reagent unload list with the ReagEx alarm.
2. Exchange expired reagents.

Reag.F

Alarm Reagent film detected

Description The reagent probe detects a film or air bubbles on the reagent.

Cause There are bubbles in the reagent bottle.

Remedy Remove bubbles with an applicator stick.

Reag.H

Alarm Reagent hovering

Description The reagent probe hovers over the reagent disk.

Cause A premature LLD signal is detected during reagent pipetting.

Remedy
1. Dry the lids on the affected **cobas e** pack. Check for bubbles in the affected **cobas e** pack.
2. Choose **Utility** > **Maintenance** and perform maintenance item (1) Reset.

Reag.T

Alarm Reagent disk temperature

Description Reagent disk temperature is out of range. The system performs an initial check 30 minutes after start-up. The temperature is checked continuously thereafter.

Cause
- Radiation of heat does not work normally.
- The room temperature is out of range.

Remedy
1. Verify that the reagent disk cover is securely in place.
2. Check the fans at the back of the module are operating normally and are free of obstructions.
3. Check that room temperature is between 18°C and 32°C (64.4°F and 89.6°F).

Reag.S

Alarm Reagent short

Description The liquid level cannot be detected in the **cobas e** pack.

Cause
- There is no reagent in the **cobas e** pack.
- The lead wire for the liquid level sensor is disconnected.

Remedy
1. Replace with a new **cobas e** pack.
2. Connect the lead wire.

>Rept / <Rept

Alarm Repeat limit over (upper / lower)

Description The result is larger than the specified upper limit value (>Rept) or smaller than the lower limit value (<Rept).

Cause
- The sample concentration is higher than the set value (>Rept).
- The sample concentration is lower than the set value (<Rept).
- An improper repeat limit range is specified.

Remedy
1. Rerun the sample and check the measured value. Or rerun the sample with its dilution.
2. Rerun the sample and check the measured value.
3. Specify a proper range for Repeat Limit (test parameter).

Samp.B

Alarm Sample air bubble

Description
- The sample probe detects air bubbles on the sample.
- Air bubble is detected in the sample syringe flow path when the sample is aspirated.

While pipetting samples, the **e** 601 module checks if there are bubbles on the surface of the sample liquid. This check, however, is performed only if the pipetting volume is more than 15 µL.

Cause
- There are bubbles in the sample container.
- There are air bubbles in the water flow tube.

Remedy
1. Remove bubbles from sample tube with an applicator stick.
2. Choose **Utility** > **Maintenance** and perform maintenance item (23) Pipetter Air Purge (10 cycles).

Samp.C

Alarm Sample clot

Description A sample clot is detected during aspiration.

Cause
- The sample volume is insufficient.
- There are clots in the sample.

Remedy
1. Fill the required volume in the sample container.
2. Check sample for fibrin. Remove any clots.

Samp.H

Alarm Sample hovering

Description The sample probe hovers over the sample.

Cause A premature LLD signal is detected during sample pipetting.

Remedy
1. Check for bubbles in the sample.
2. Choose **Utility** > **Maintenance** and perform maintenance item (1) Reset.

Samp.O

Alarm Potential carryover during processing of the rerun measurement

Description If a sample probe wash is defined for an e 601 test and this test is requested for a sample that has been already measured, the Samp.O flag is attached to the test result.

For information about defining a sample probe wash for photometric tests, see *Sample probe wash* on page B-305.

Cause Required measurement condition does not correspond to sample probe wash configuration for this test.

Remedy Repeat measurement with a new sample aliquot.

Samp.S

Alarm Sample short

Description The liquid level cannot be detected in the sample container.

Cause The sample volume is insufficient in the sample container.

Remedy
1. Add sample and rerun.
2. Resume operation.
3. If alarm recurs, call Roche service representative.

<SigL

Alarm Low signal level

Description The signal level is extraordinarily low.

Cause
- The volume of the reaction mixture in the AssayCup is insufficient
- Reaction mixture contain clots

Remedy Rerun the sample

Cause Extremely high sample concentration for a competitive assay

Remedy Rerun manually diluted sample.

Cause Abnormal MC condition of detection unit (sipper/tubing/MC)

Remedy If alarm recurs, call Roche service representative.

SLLD.E

Alarm Sample LLD abnormal

Description The sample probe does not start LLD or LLD is not completed.

Cause
1. The tip of the sample probe is dirty.
2. The tip of the sample probe is wet.

Remedy
1. Clean the tip of the sample probe and resume measurement. If the alarm recurs, call Roche service representative.
2. Dry the tip of the sample probe and resume measurement. If the alarm recurs, call Roche service representative.

SLLD.N

Alarm Sample LLD noise

Description The sample probe detects air bubbles on the sample.

Cause
1. The sample volume is insufficient.
2. There are bubbles in the sample container.

Remedy
1. Check sample volume.
2. Remove the bubbles with an applicator stick.

SysR.S

Alarm Auxiliary reagent short

Description The counted remaining number becomes 0, liquid short signal is detected, or the liquid level cannot be detected in the ProCell reservoir.

Cause There is no reagent in the reagent bottle.

Remedy Replace with new ProCell/CleanCell bottles.

SysR.T

Alarm Auxiliary reagent temperature

Description ProCell/CleanCell temperature is out of range. The system performs an initial check 30 minutes after start-up. The temperature is checked continuously thereafter.

Cause
1. Radiation of heat does not work normally.
2. The room temperature is out of range.

Remedy
1. Check the fans at the rear part of the module are operating normally and are free of obstructions.
2. Check that room temperature is between 18°C and 32°C (64.4°F and 89.6°F).

>Test / <Test

Alarm Upper/Lower technical Limit

Description
- Upper technical limit exceeded:

 The measured value is higher than the measuring range (>Test) coded in the **cobas e** pack barcode.
- Lower technical limit exceeded:

 The measured value is lower than the measuring range (<Test) coded in the **cobas e** pack barcode.

Cause
- The sample concentration is above the upper limit of the measuring (reportable) range (>Test).
- The sample concentration is below the lower limit of the measuring (reportable) range (<Test).

Remedy
1. If >Test, rerun using the recommended dilution and check the measured value.
2. If <Test, report the result as less than the lower detection limit of the assay. Rerun is not requested.

WB.S

Alarm Washing buffer short (PreClean)

Description The remaining volume for PreClean is 0, or liquid short signal is detected.

Cause There is no reagent in the reagent bottle.

Remedy Replace with a new PreClean bottle.

WB.T

Alarm Washing buffer temperature (PreClean)

Description PreClean temperature is out of range. The system performs an initial check 30 minutes after start-up. The temperature is checked continuously thereafter.

Cause
1. Radiation of heat does not work normally.
2. The room temperature is out of range.

Remedy
1. Check the fans at the rear part of the module are operating normally and are free of obstructions.
2. Check that room temperature is between 18°C and 32°C (64.4°F and 89.6°F).

Data alarms for calibrations

The following table displays all calibration data alarms applicable to ISE tests, **c** 501 tests, **e** 601 tests, and their presentation (flag) on screens and reports.

Flag	Alarm	c 501(ISE)	c 501(P)	e 601
Cal.E	CALIB error (Calib flag – c 501 (ISE))	✓	–	–
Cond.E	Conditioning (ISE) abnormal	✓	–	–
Diff.E	Minimum acceptable difference	–	–	✓
Dup.E	Duplicate error (c 501)	–	✓	–
Dupl.	Duplicate error (e 601)	–	–	✓
IStd.E	Internal standard concentration abnormal	✓	–	–
Mono.E	Monotony of curve	–	–	✓
Prep.E	Preparation abnormal	✓	–	–
Rsp1.E	Response (ISE) abnormal 1	✓	–	–
Rsp2.E	Response (ISE) abnormal 2	✓	–	–
S1A.E	S1ABS abnormal	–	✓	–
SD.E	SD limit error	–	✓	–
Sens.E	Sensitivity error	–	✓	–
>Sig	Maximum signal	–	–	✓
<Sig	Minimum signal	–	–	✓
Sig.E	Minimum/Maximum signal	–	–	✓
Slop.E	ISE slope abnormal	✓	–	–
Std.E	Standard error	✓	✓	–
Sys.E	System error	–	–	✓

Table D-5 Data alarm list

Cal.E

Alarm CALIB error (Calib flag – **c** 501 (ISE))

Displayed in **Calibration** > **Status** > **Calibration Trace**.

Description The current calibrator concentration value or slope value differs from the previous one by more than the specified **Compensated Limit**. The **Compensated Limit** is a limit for the difference | previous value – current value | expressed as percentage of the average (previous value + current value)/2.

The Cal.E alarm is a warning only, not necessarily indicative of a problem with the calibration. Check the test's control recovery before accepting the new calibration result.

Cause
- The standard solution or reagent is not placed in proper position.
- The reagent has deteriorated or the standard solution has become concentrated due to evaporation.

Remedy
- Correct any other instrument and/or data alarms.
- Check standards, reagents, and controls. If controls are in range, and standards and reagents are acceptable, resume operation. Otherwise, correct abnormalities and recalibrate.
- Check Compensated Limit on **Utility** > **Application** > **Calib**.

Cond.E

Alarm Conditioning (ISE) abnormal

Description The slope value is 68.1 mV or greater for Na^+ or K^+ electrodes, or it is -68.1 mV or less for the Cl^- electrode. The conditioning is inadequate.

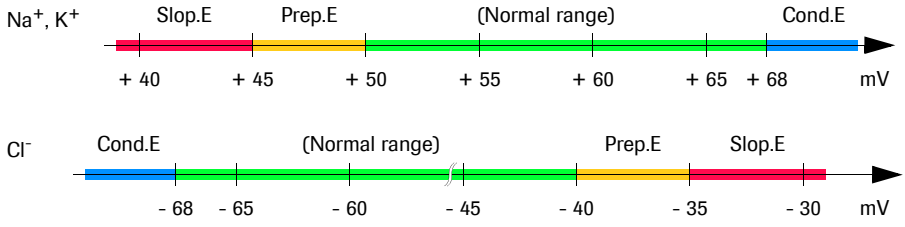


Figure D-4 ISE data alarms and corresponding slope values (EMF values)

Cause
- Conditioning of a new electrode is unsatisfactory.
- The concentration of standard solution LOW/HIGH is improper.

Remedy
1. Run 10 dummy samples of human serum.
2. Pour fresh calibrator ISE Low [Std (1)], ISE High [Std (2)], and ISE High [Std (3)], place on calibration rack and recalibrate the ISEs.
3. Resume operation. If alarm recurs, call Roche service representative.

Diff.E

Alarm Minimum acceptable difference

Description The difference of the signals between each level of calibrators is below the permissible value.

Cause
- The ProCell or calibrator is expired.
- The calibrator does not reach room temperature.

Remedy
1. Replace ProCell.
2. Set the calibrator appropriately.

Dup.E

Alarm Duplicate error (**c** 501)

Displayed in **Calibration** > **Status** > **Calibration Trace**.

Description The difference between the first and second measurement (absorbance) of a calibrator is outside the specified range.

The following steps describe how a decision is made to flag a calibration for violating the duplicate limit.

1. The absorbance for a calibrator (N) is measured twice.
2. The % of error and absorbance error are computed.
3. Is the absorbance error < Duplicate Limit Abs. that appears on **Utility** > **Application**?

 If no, go to step 5.

 If yes, go to step 4.
4. Continue with result calculations. No Dup.E alarm is issued.
5. Is the % error < the % Duplicate Limit?

 If no, go to step 6.

 If yes, go to step 4.
6. Dup.E alarm is issued for this result.

Cause The difference between the first and second measurement (absorbance) of a calibrator is greater than Duplicate Limit Abs and greater than the % Duplicate Error.

Remedy
1. Recalibrate.
2. Check reagent storage, handling and expiration date. Replace the reagent if necessary and recalibrate.
3. If alarm recurs, call Roche service representative.



If this alarm occurs, a Std.E alarm is issued. The Std.E alarm prevents updating of calibration for the affected test.

Dupl.

Alarm Duplicate error (**e** 601)

Displayed in **Calibration** > **Status** > **Calibration Result**.

Description The difference between the first and second measured signal of the calibrator is out of the range specified in the assay.

Cause
- Air was aspirated during the first determination due to air bubbles on the corresponding calibrator. During the second determination no air was aspirated.
- Consequence: The signal values of the first and second determination differ more than the specified percentage.

Remedy
1. Verify that there are not air bubbles on the surface of the calibrator and perform a new calibration.

IStd.E

Alarm Internal standard concentration abnormal

Displayed on **Calibration** > **Status** > **Calibration Trace**

Description The concentration of the internal standard solution (ISE IS) was not within the following ranges:

Na^+	120.0-160.0 mmol/L
K^+	3.0-7.0 mmol/L
Cl^-	80.0-120.0 mmol/L

Cause
- The flow path is contaminated.
- The reagent has deteriorated.

Remedy
1. If the EMF of ISE IS is abnormal on the calibration report, check the ISE IS reagent volume. If necessary, perform a reagent prime and recalibrate.
2. If the EMF of ISE IS is normal on the calibration report, check ISE reagent syringe. The EMF of ISE IS lies ideally midway between the low and the high standard. The ideal ISE IS concentrations values are: Na^+: 140 mmol/L; K^+: 5 mmol/L; Cl^-: 100 mmol/L.
3. Resume operation. If alarm recurs, call Roche service representative.
4. Perform maintenance item (8) Reagent Prime for the ISE unit to wash the flow path.
5. Replace the internal standard solution and recalibrate.

Mono.E

Alarm Monotony of curve

Description The working curve is not monotonically increasing or monotonically decreasing.

Cause
- The ProCell or calibrator is expired.
- The calibrator did not reach room temperature.

Remedy
1. Replace ProCell.
2. Place the calibrator appropriately.

Prep.E

Alarm Preparation abnormal

Displayed on **Calibration** > **Status** > **Calibration Trace**.

Description The slope value is within the following range: 45.0 to 49.9 mV for Na^+ or K^+ electrodes, -39.9 to -35.0 mV for the Cl^- electrodes.

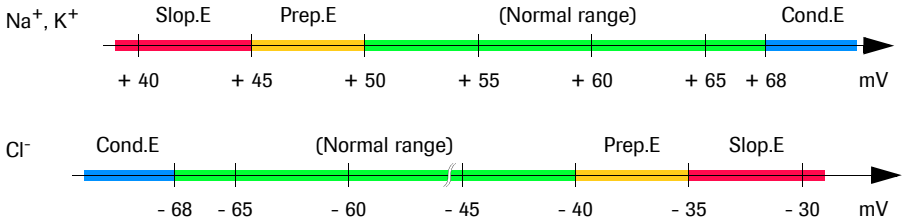


Figure D-5 ISE data alarms and corresponding slope values (EMF values)

Cause
- The electrode is deteriorated.
- The flow path is contaminated.

Remedy
1. Replace the electrode.

Replacing ISE cartridges must only be done by specially trained operators.

For more information, refer to the separate maintenance manual: *Interlock function cobas* **c** 501 *with ISE.*

2. Perform maintenance item (8) Reagent Prime to prime the lines.

Rsp1.E

Alarm Response (ISE) abnormal 1

Description The compensation factor is over the limits (narrower range).

Cause
- The flow path is contaminated.
- The electrode is contaminated or deteriorated.

Remedy
1. Check ISE controls for correct levels.
2. If incorrect, go to step 3 before continuing routine analysis. If correct, go to step 3 after finishing routine analysis at the end of the day.
3. Perform the green wash rack procedure.
 For information on processing the green wash rack, see *Processing green wash rack* on page C-69.
4. Run 10 dummy samples of human serum.
5. Prepare fresh calibrator; place on calibration rack and recalibrate the ISEs.
6. Resume operation. If alarm recurs, repeat steps 3 through 5 a maximum of two times. If alarm recurs, replace the ISE cartridges.

Rsp2.E

Alarm Response (ISE) abnormal 2

Description The compensation factor is over the limits (wider range).

Cause
- The flow path is contaminated.
- The electrode is contaminated or deteriorated.

Remedy See *Rsp1.E* on page D-48.

S1A.E

Alarm S1ABS abnormal

Displayed in **Calibration** > **Status** > **Calibration Trace**.

Description During calibration, expected absorbance is outside the S1 Abs Limit. S1 is read bichromatically for endpoint assays, monochromatically for rate assays.

Cause
- The reagent has been stored or handled improperly or has deteriorated.
- An improper absorbance range is specified for calibrator 1.

Remedy
1. Check reagent storage and handling and calibrator preparation, if applicable.
2. Recalibrate.
3. Check S1 Abs. Limit values on **Utility** > **Application** > **Calib**.
4. Resume operation. If alarm recurs, call Roche service representative.

SD.E

Alarm SD limit error

Description During nonlinear or multipoint linear calibration, the SD value was larger than the SD limit programmed on **Utility** > **Application**.

The result of the calibration is not updated.

Cause
- The calibrator is not placed at a correct position.
- An improper SD limit value is specified.

Remedy
1. Check calibrator positions on **Calibration** > **Calibrator**
2. Choose **Utility** > **Application** > **Calib**. to check the SD limit.
3. Check reagent storage and handling and calibrator preparation. Recalibrate the affected test.
4. Check the standard concentrations on **Calibration** > **Install**. For a calibration with automatic standard dilution; check whether the ratio between concentration, sample, diluent volume and diluted sample is correct on **Utility** > **Application** > **Others**.
5. Resume operation. If alarm recurs, call Roche service representative.

Sens.E

Alarm Sensitivity error

Sensitivity is checked for linear (2 to 6 points), nonlinear, or isozyme-P calibration. This alarm is indicated if the sensitivity value obtained in a calibration falls out of the sensitivity limits specified on **Utility** > **Application** > **Calib**.

A sensitivity value is calculated from the measured absorbance values (Abs) and given concentration values ($Conc$) of the blank calibrator (S_1) and the calibrator S_N:

$(Abs(S_N) - Abs(S_1))/(Conc(S_N) - Conc(S_1))$, where

S_N = Std 2 for 2 Point calibrations and span calibrator for multipoint calibrations

For span calibration, the previous S1 Abs (linear) or previous mean absorbance (nonlinear) of calibrator (1) is used for the sensitivity check.

Cause
- The calibrator is not placed at a proper position.
- The reagent has been prepared improperly or has deteriorated.

 An improper sensitivity limit is specified.

Remedy
1. Check preparation and expiration dates of calibrators and reagents. Recalibrate the affected test.
2. Check sample pipetter for leaks and recalibrate the affected test.
3. Choose **Utility** > **Application** > **Calib**. to check the sensitivity limit and recalibrate the affected test.
4. Resume operation. If alarm recurs, call Roche service representative.

>Sig

Alarm Maximum signal

Description The calibrator signal is larger than the specified upper limit value coded in the **cobas e** pack barcode. Only for qualitative assays.

Cause
- The ProCell calibrator is expired.
- The calibrator does not reach room temperature.

Remedy
1. Replace ProCell.
2. Place the calibrator appropriately.

<Sig

Alarm Minimum signal

Description The calibrator signal is lower than the specified lower limit value coded in the **cobas e** pack barcode. For qualitative and quantitative assays.

Cause
- The ProCell or calibrator is expired.
- The calibrator does not reach room temperature.

Remedy
1. Replace ProCell.
2. Place the calibrator appropriately.

Sig.E

Alarm Minimum/Maximum signal

Description The measured signal of a calibrator for a qualitative test should fall between the designated minimum and maximum signal. If one or more values fall out of the allowable minimum/maximum signal range, the calibration fails.

Cause The measured signal of a calibrator for a qualitative test lies outside the designated minimum/maximum signal range.

Remedy
1. Check the calibrators and reagents and repeat the calibration.
2. Set new calibrators and a **cobas e** pack if necessary, and repeat calibration.

Slop.E

Alarm ISE slope abnormal

Displayed on **Calibration** > **Status** > **Calibration Trace**.

Description The slope value is less than 45.0 mV for Na^+ or K^+ electrodes, or greater than -35 mV for the Cl^- electrode.

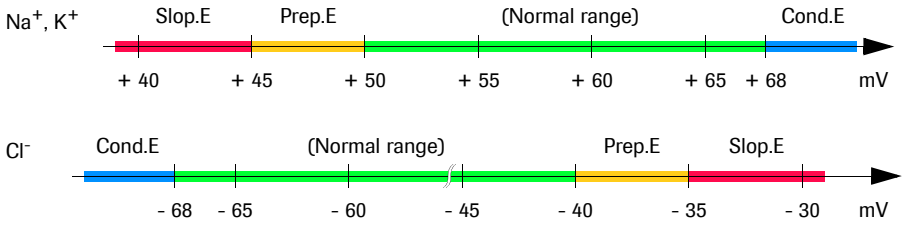


Figure D-6 ISE data alarms and corresponding slope values (EMF values)

Cause

- The electrode is deteriorated.
- Standard solutions Low and High are not placed in the proper positions.
- The sample probe is clogged.

Remedy

1. Replace the appropriate ISE cartridge before continuing routine analysis.

Replacing ISE cartridges must only be done by specially trained operators.

For more information, refer to the separate maintenance manual: *Interlock function cobas* **c** 501 *with ISE.*

2. Run 10 dummy samples of human serum.
3. Prepare fresh calibrator; place on calibration rack and recalibrate the ISEs.
4. Resume operation. If alarm recurs, call Roche service representative.

Std.E

This section describes the Std.E alarm for the ISE and photometric unit of the **c** 501 module.

c 501 (ISE)

Alarm Standard error

Description

1. During ISE calibration, any one of the following alarms was encountered:

Data alarm	Data flag
ADC abnormal	ADC.E
Calculation not possible	Calc.?
ISE voltage level error	ISE.E
ISE noise error	ISE.N
Mixing power low level	<Mix
Ultrasonic mixing error	Mix.E
Sample short	Samp.S

Table D-6 Data alarms giving rise to a Std.E alarm when occurring during calibration

2. During calibration, calculation was disabled.



The calibration is not updated if this alarm is issued; i.e. the prior calibration remains in effect.

Cause

- The reagent is empty and has to be replaced.
- The concentration of calibrator is improper or the calibrator is not placed in the proper position.
- An improper check value is specified.

Remedy

1. Correct any other instrument and/or data alarms.
2. Prepare fresh calibrator; place on the rack and recalibrate.
3. Replace reagent, prime, and recalibrate.
4. Choose **Utility** > **Application** to check the calibration parameters.
5. Resume operation. If alarm recurs, call Roche service representative.

c 501 (P)

Alarm Standard error

Description

1. During photometric calibration, any one of the following alarms was encountered:

Data alarm	Data flag
ABS over	>Abs
ADC abnormal	ADC.E
Calculation not possible	Calc.?
Cell blank abnormal	>Cuvet
Duplicate error (c 501)	Dup.E
Linearity abnormal	>Lin
Mixing power low level	<Mix
Ultrasonic mixing error	Mix.E
Prozone error 1, Prozone error 2 / Kinetic unstable	>Proz, >Kin[(a)]
Reaction limit over (substrate depletion)	>React
Reagent short	Reag.S
S1ABS abnormal	S1A.E
Sample short	Samp.S

Table D-7 Data alarms giving rise to a Std.E alarm when occurring during calibration
(a) Not for Std.1

2. During calibration, calculation was disabled.
3. During nonlinear calibration, an extreme value appeared.

The calibration is not updated if this alarm is issued; i.e. the prior calibration remains in effect.

Cause

- The reagent has not been stored or handled properly or is empty and has to be replaced.
- The concentration of calibrator is improper or the calibrator is not placed in the proper position.
- An improper check value is specified.

Remedy

1. Correct any other instrument and/or data alarms.
2. Prepare fresh calibrator; place on the rack and recalibrate.
3. Replace reagent and recalibrate.
4. Choose **Utility** > **Application** to check the calibration parameters.
5. Resume operation. If alarm recurs, call Roche service representative.

Sys.E

Alarm System error

Description An error occurs on the system during measurement.

Cause Check the **Alarm** screen.

Remedy Eliminate problems with the instrument, referring to the **Alarm** screen.

Data alarms for controls

The following table displays the control data alarms applicable to ISE tests, **c** 501 tests, **e** 601 tests, and their presentation (flag) on screens and reports.

Flag	Alarm	c 501(ISE)	c 501(P)	e 601
>AB	AB level range over (Assay Buffer=ProCell)	–	–	✓
AB.E	AB level check error	–	–	✓
>Abs	ABS over	–	✓	–
ADC.E	ADC abnormal	✓	✓	✓
Cal.E (Sample flag)	Calibration result abnormal (Sample flag)	✓	✓	✓
Calc.?	Calculation not possible	✓	✓	✓
CarOvr	Potential microbeads carryover	–	–	✓
Cell.T	Measuring cell temperature out of range	–	–	✓
ClcT.E	Calculated test error	✓	✓	–
Clot.E	Clot pressure abnormal	–	–	✓
CmpT.?	Unable to calculate compensated test	✓	✓	–
CmpT.E	Data error in compensated test	✓	✓	–
>Curr	Current range over	–	–	✓
Curr.E	Current range check error	–	–	✓
>Cuvet	Cell blank abnormal	–	✓	–
Det.S	Carry over detergent short	–	✓	–
Inc.T	Incubator temperature	–	–	✓
ISE.E	ISE voltage level error	✓	–	–
ISE.N	ISE noise error	✓	–	–
>Lin	Linearity abnormal	–	✓	–
Mix.E	Ultrasonic mixing error	✓	✓	–
<Mix	Mixing power low level	✓	✓	–
Over.E	Overflow	✓	✓	✓
Q2.5SD	1-2.5SD (QC error 2)	✓	✓	✓
Q3SD	1-3SD (QC error 1)	✓	✓	✓
R4SD	R-4S (Random error in realtime QC)	✓	✓	✓
>React	Reaction limit over (substrate depletion)	–	✓	–
ReagEx	Reagent expired	–	✓	✓
Reag.F	Reagent film detected	–	–	✓
Reag.H	Reagent hovering	–	–	✓
Reag.S	Reagent short	✓	–	✓
Reag.T	Reagent disk temperature	–	–	✓
S2-2Sa	2-2SA (Syst. error 1 – 2 results)	✓	✓	✓
S2-2Sw	2-2SW (Syst. error 2 – 2 samples / 4 results)	✓	✓	✓
S4-1Sa	4-1SA (Syst. error 3 – 4 results)	✓	✓	✓
S4-1Sw	4-1SW (Syst. error 4 – 4 samples / 8 results)	✓	✓	✓
S10Xa	10XA (Syst. error 5 – 10 results)	✓	✓	✓
S10Xw	10XW (Syst. error 6 – 10 samples / 20 results)	✓	✓	✓

Table D-8 Data alarm list (Sheet 1 of 2)

Flag	Alarm	c 501(ISE)	c 501(P)	e 601
Samp.?	ABS maximum over (non-lin curve)	–	✓	–
Samp.B	Sample air bubble	–	–	✓
Samp.C	Sample clot	✓	✓	✓
Samp.H	Sample hovering	–	–	✓
Samp.S	Sample short	✓	✓	✓
<SigL	Low signal level	–	–	✓
SLLD.E	Sample LLD abnormal	–	–	✓
SLLD.N	Sample LLD noise	–	–	✓
SysR.S	Auxiliary reagent short	–	–	✓
SysR.T	Auxiliary reagent temperature	–	–	✓
< >Test	Sample range over	✓	–	–
>Test / <Test	Upper/Lower technical Limit	–	–	✓
WB.S	Washing buffer short (PreClean)	–	–	✓
WB.T	Washing buffer temperature (PreClean)	–	–	✓

Table D-8 Data alarm list (Sheet 2 of 2)

Q3SD

Alarm 1-3SD (QC error 1)

Description In Realtime QC, the control X or control Y data value is above 3 SD or below -3 SD.

Cause
- Reagent is deteriorated
- Poor precision due to leakage of the pipetter joint
- Proper control values (mean value, standard deviation) are not specified.

This check is performed only when RULE 1-3 SD is selected.

Remedy
1. Check that calibrators, controls and reagents are properly prepared, positioned, and stored.
2. Check that the mean and SD for the specified assays are entered correctly on **QC** > **Install**.
3. Check that calibrator values are correct, if available, on **Calibration** > **Install**.
4. Register a new reagent cassette or **cobas e** pack.
5. Check the pipetter (**Maintenance Check**).

Q2.5SD

Alarm 1-2.5SD (QC error 2)

Description In Realtime QC, the control X value or control Y data value is above 2.5 SD or below -2.5 SD.

Cause
- The reagent is deteriorated (linearity of working curve degraded).
- One control is concentrated or deteriorated.

This check is performed only when RULE 1-2.5SD is selected.

Remedy
1. Register new reagent cassette or replace with a new **cobas e** pack.
2. Prepare a new control. Prepare control X together with control Y and use them for a given period of time.

R4SD

Alarm R-4S (Random error in realtime QC)

Description On Realtime QC, one of X and Y data values is above 2 SD and the other is below -2 SD.

Cause
- The control X and control Y are not set at proper positions.
- Reagent is deteriorated.

This check is performed only when RULE R-4SD is selected. N = run size entered on **Select Rules** window.

Remedy
1. Check that calibrators, controls, and reagents are properly prepared and stored.
2. Check that calibrators and controls are properly positioned on the system.
3. Check proper lot number and expiration dates of calibrators, controls and reagents.
4. Check that the mean and SD for the specified assay are entered correctly on **QC** > **Install**.
5. Check that calibrator values are correct on **Calibration** > **Install**.
6. Resume operation. If alarm recurs, call Roche service representative.

S2-2Sa

Alarm 2-2SA (Syst. error 1 – 2 results)

Description The control X and Y values are above 2 SD or below -2 SD.

Cause
- The calibrators or controls are not properly prepared.
- The controls are not properly positioned on the system.

This check is performed only when RULE 2-2SD is selected.

Remedy
1. Check that calibrators, controls, and reagents are properly prepared and stored.
2. Check that calibrators and controls are properly positioned on the system.
3. Check proper lot number and expiration dates of calibrators, controls and reagents.
4. Check that the mean and SD for the specified assay are entered correctly on **QC** > **Install**.
5. Check that calibrator values are correct on **Calibration** > **Install**.
6. Resume operation. If alarm recurs, call Roche service representative.

S2-2Sw

Alarm 2-2SW (Syst. error 2 – 2 samples / 4 results)

Description The last two control X or last two control Y values were above 2 SD or below -2 SD.

Cause
- The calibrators or controls are not properly prepared.
- The reagents are not properly prepared.

This check is performed only when RULE 2-2SD is selected.

Remedy See *Remedy* of *S2-2Sa* on page D-58.

S4-1Sa

Alarm 4-1SA (Syst. error 3 – 4 results)

Description On realtime QC the last two X and Y data values are above +1 SD or below -1 SD.

Cause
- The calibrators or controls are not properly prepared.
- The reagents are not properly prepared.

This check is performed only when RULE 4-1SD is selected.

Remedy See *Remedy* of *S2-2Sa* on page D-58.

S4-1Sw

Alarm 4-1SW (Syst. error 4 – 4 samples / 8 results)

Description The last four control X or last four control Y values are above 1 SD or below -1 SD.

Cause
- The calibrators or controls are not properly prepared.
- The reagents are not properly prepared.

This check is performed only when RULE 4-1SD is selected.

Remedy See *Remedy* of *S2-2Sa* on page D-58.

S10Xa

Alarm 10XA (Syst. error 5 – 10 results)

Description On realtime QC the last five X and Y data values fall on the + or - side of the mean value.

Cause
- The calibrators or controls are not properly prepared.
- The reagents are not properly prepared.

This check is performed only when RULE 10X is selected.

Remedy See *Remedy* of *S2-2Sa* on page D-58.

S10Xw

Alarm 10XW (Syst. error 6 – 10 samples / 20 results)

Description The last 10 control X or last 10 control Y values are positive-above the mean value or negative-below the mean value.

Cause The mean value specified for one control is improper.

This check is performed only when RULE 10X is selected.

Remedy See *Remedy* of *S2-2Sa* on page D-58.

Data problems without alarm

This chapter provides general information about data problems on the **cobas** 6000 analyzer series instrument without alarm.

Drift of result data

Cause
- Concentration or deterioration of sample
- The calibrator is concentrated or deteriorated.
- The reagent flow path is contaminated. (ISE unit)

Remedy
1. Avoid leaving the sample in the sample cup for a long time.
2. Perform maintenance item (19) System Wash.

Erroneous operation

Cause
- Neglect of preliminary or periodical check(s).
- Carryover between tests.
- Fibrin contained in sample or dust contained in reagent.
- The sample container that was used was not recommended.

Remedy
1. Carry out preliminary and/or periodical check according to the specified procedure.
2. Change the channel, use the wash program, or take any other measure after consulting with the reagent manufacturer.
3. Eliminate fibrin or dust. Be sure to check the sample and reagent before setting them.
4. Perform maintenance item (12) Sample Probe Wash.
5. Use the recommended sample container.

Poor reproducibility

Cause
- A maintenance item is overdue.
- Deterioration of reagent or precipitation of insoluble matter.
- Deterioration of ProCell, CleanCell, or PreClean.
- Poor deionized water quality.
- Reagent handling was not done as recommended.
- Test parameters are not set properly.

Remedy
1. Carry out daily checks and periodical maintenance according to the specified maintenance procedure.
2. Replace with a new reagent cassette or **cobas e** pack. Do not add or mix old and new reagent.
3. Replace with new ProCell/CleanCell or PreClean bottles.
4. The water quality must be 1 µS/cm (microsiemens per cm) or less.
5. Use the recommended reagent handling.
6. Check the completeness of the special wash list. If necessary, install the special wash list according to the recommendation of the manufacturer.
7. Check the application setting of the Open/Close mode in **Utility** > **Application** > **Analyze**. The usage of the Cap Open/Close mode *open upon pipetting* is recommended for all tests in order to guarantee maximum reagent stability.

Result data at high level

Cause
- Concentration of control or sample.
- Deterioration of calibrator.
- Deterioration of ProCell or CleanCell (**e** 601).
- The reagent, control and standard handling were not done as recommended.

Remedy
1. Avoid leaving the sample or control in the sample cup for long time.
2. Avoid leaving the calibrator cup open for a long time.
3. Replace with new ProCell/CleanCell bottles.
4. Use the recommended reagent, control and calibrator handling.

Result data at low level

Cause
- Concentration of calibrator.
- Reagent storage or handling was not done as recommended.
- The test parameters are not set properly.
- Deterioration of ProCell or CleanCell (**e** 601).

Remedy
1. Use the calibrator immediately after opening the cap of the vial.
2. Replace the reagent.
3. Set the concentration of calibrator properly (not for **e** 601).
4. Replace with new ProCell/CleanCell bottles.

Trouble attributed to characteristics of reagent

Cause
- Cross contamination (high value, low value)
- Coloring matter adheres to the reaction cell.

Remedy
1. Perform maintenance item (7) Wash Reaction Parts.
2. Check whether the special wash list is complete. Install the special wash list according to the recommendations of the manufacturer.
See *Special Wash* on page B-297.

Trouble for each test

Cause
- Improper preparation or management of calibrator or control (high value, low value).
- Improper management of reagent (low value).

Remedy
1. Prepare a new calibrator or control.
2. Replace with a new reagent cassette or **cobas e** pack.
3. Set the test parameters properly according to the setting table given by the reagent manufacturer.

Trouble on each analytical module

Cause
- Air bubbles in the sample or reagent syringe (poor reproducibility).
- Liquid leakage from sample or reagent syringe (poor reproducibility).
- Deterioration of ProCell, CleanCell, or PreClean (**e** 601).

Remedy
1. Carry out maintenance and inspection.
2. Replace with new ProCell/CleanCell or PreClean bottles.

Trouble on each channel in same module

Cause
- Air bubbles in the sipper syringe (poor reproducibility).
- Liquid leakage from sipper syringe (poor reproducibility).
- The electrode of the measuring cell is contaminated or deteriorated (high value or low value).

Remedy
1. Call Roche service representative.
2. Perform maintenance item (27) Liquid Flow Cleaning according to the specified procedure.

Rerun list

The following table indicates whether a rerun is automatically *requested* by the system when a data alarm is attached to a result. The rerun conditions are displayed under **c** 501 (ISE unit, Photometric unit) and **e** 601 module, respectively. The automatic rerun column indicates whether a rerun is automatically *performed* by the system.

For more information on performing reruns, see *Processing reruns* on page B-67.

Increase	Sample is rerun at an increased sample concentration
Normal	Sample is rerun at same sample concentration (repeat)
Decrease	Sample is rerun at a decreased sample concentration
No rerun	No rerun is performed on this module

Flag	Alarm	c 501 (ISE)	c 501 (P)	e 601	Auto rerun
>AB	AB level range over (Assay Buffer=ProCell)	-	-	Normal	Yes
AB.E	AB level check error	-	-	Normal	Yes
>Abs	ABS over	-	Decrease	-	Yes
ADC.E	ADC abnormal	Normal	Normal	Normal	Yes
Cal.E	Calibration result abnormal (Sample flag)	Normal	Normal	Normal	No
Calc.?	Calculation not possible	Normal	Normal	Normal	Yes
CarOvr	Potential microbeads carryover	-	-	Normal	Yes
Cell.T	Measuring cell temperature out of range	-	-	Normal	Yes
ClcT.E	Calculated test error	No rerun	No rerun	-	No
Clot.E	Clot pressure abnormal	-	-	Normal	Yes
CmpT.?	Unable to calculate compensated test	Normal	Normal	-	Yes
CmpT.E	Data error in compensated test	Normal	Normal	-	Yes
>Curr	Current range over	-	-	Normal	Yes
Curr.E	Current range check error	-	-	Normal	Yes
>Cuvet	Cell blank abnormal	-	Normal	-	Yes
Det.S	Carry over detergent short	-	Normal	-	No
Edited	Edited test	No rerun	No rerun	No rerun	No
Inc.T	Incubator temperature	-	-	Normal	Yes
>Index	Serum index check	No rerun	No rerun	-	No
>I.xxx	Serum index check	No rerun	No rerun	-	No
ISE.E	ISE voltage level error	Normal	-	-	Yes
ISE.N	ISE noise error	Normal	-	-	Yes
>Kin	Prozone error 2 / Kinetic unstable	-	Decrease	-	Yes
>Lin	Linearity abnormal	-	Normal	-	Yes
Mix.E	Ultrasonic mixing error	Normal	Normal	-	Yes
<Mix	Mixing power low level	Normal	Normal	-	Yes
Over.E	Overflow	No rerun	No rerun	No rerun	No

Table D-9 Rerun list (Sheet 1 of 2)

(a) For urine: Decrease sample volume can only be requested manually.

(b) A rerun is not performed if the normal and increase volumes (**Utility** > **Application** > **Analyze**) are identical.

Rerun list

Flag	Alarm	c 501 (ISE)	c 501 (P)	e 601	Auto rerun
>Proz	Prozone error 1	-	Decrease	-	Yes
>React	Reaction limit over (substrate depletion)	-	Decrease	-	Yes
ReagEx	Reagent expired	-	No rerun	No rerun	No
Reag.F	Reagent film detected	-	-	Normal	Yes
Reag.H	Reagent hovering	-	-	Normal	Yes
Reag.S	Reagent short	Normal	Normal	Normal	No
Reag.T	Reagent disk temperature	-	-	Normal	Yes
>Rept / <Rept	Repeat limit over (upper / lower)	Normal	Normal	Normal	Yes/No due to setting
Samp.?	ABS maximum over (non-lin curve)	-	Decrease	-	Yes
Samp.B	Sample air bubble	-	-	Normal	Yes
Samp.C	Sample clot	Normal	Normal	Normal	No
Samp.H	Sample hovering	-	-	Normal	Yes
Samp.O	Potential carryover during processing of the rerun measurement	-	Normal	Normal	No
Samp.S	Sample short	Normal	Normal	Normal	No
<SigL	Low signal level	-	-	Normal	Yes
SLLD.E	Sample LLD abnormal	-	-	Normal	Yes
SLLD.N	Sample LLD noise	-	-	Normal	Yes
SysR.S	Auxiliary reagent short	-	-	Normal	Yes
SysR.T	Auxiliary reagent temperature	-	-	Normal	Yes
< >Test	Sample range over	Normal	-	-	Yes
>Test	Upper technical Limit	For urine: Decrease[a] For other sample types: Normal	Decrease	Decrease	**c** 501: Yes **e** 601: Yes
< Test	Lower technical Limit	Normal	Increase[b]	No rerun	**c** 501: Yes **e** 601: No
WB.S	Washing buffer short (PreClean)	-	-	Normal	Yes
WB.T	Washing buffer temperature (PreClean)	-	-	Normal	Yes

Table D-9 Rerun list (Sheet 2 of 2)

(a) For urine: Decrease sample volume can only be requested manually.

(b) A rerun is not performed if the normal and increase volumes (**Utility** > **Application** > **Analyze**) are identical.

Troubleshooting

This chapter provides general information about troubleshooting problems on the **cobas** 6000 system.

In this chapter *Chapter* 20

General troubleshooting D-67
Troubleshooting procedures D-67
Operator's primary responsibility D-68
Calling Roche service representative D-68
Chemistry problem D-68
Immunoassay problem D-69
Instrument problem D-69
Instrument troubleshooting D-70
Troubleshooting at Power Up D-70
General instrument troubleshooting D-71
General mechanical problem isolation D-71
Electrical power not available D-71
Cannot access another software screen D-72
Touchscreen does not come on D-72
Touchscreen is difficult to see D-72
Probes do not descend to liquid surface D-73
Bubbles in syringes D-73
c 501 (ISE) troubleshooting D-74
ISE, all results are erratic, excessive air in sipper syringe D-74
ISE, results are erratic D-75
ISE, high internal standard values D-76
ISE, high sodium or low chloride values D-77
Low ISE values D-77
c 501 (P) troubleshooting D-78
High test results D-78
Low test results D-79
Erratic test results D-79
Erratic or biased test results D-81
Single sample or control D-82
Single test (1 reagent) D-82

Tests with more than 1 calibration point D-83
Multiple photometric tests (more than 1 reagent) D-83
All photometric tests D-84
Biased enzyme results D-84
e 601 troubleshooting D-85
Reagent disk cover does not open/close D-85
Trouble replacing ProCell/CleanCell D-85
Trouble replacing PreClean D-86
Drift D-86
Erratic test results D-86
Assay calibration D-87
Calibration cannot be performed D-87
Calibration not released D-87
Duplicates out of limits D-88
Monotony not fulfilled D-88
Missing values D-88
Values out of limits D-89
Calibration factor out of limits D-90
Recovery of controls D-91
Intra assay precision D-91
Inter assay precision (including both channels within 1 module) D-92
Module to module variance D-92
Method comparison D-93

General troubleshooting

This chapter provides general information about troubleshooting problems on the **cobas** 6000 system.

Troubleshooting procedures

To identify and isolate problems effectively, you must understand the theory of operation, operating procedures, emergency procedures and test reaction descriptions covered in this manual. The following areas are covered:

For more information, see:
Application problems on page D-67
Instrument problems on page D-67
Computer problems on page D-67
Facility problems on page D-67
Operator's primary responsibility on page D-68

Application problems
- Photometric, immunoassay or ISE
- Reagents
- Samples, controls or calibrators
- Operator error.

Instrument problems
- Electrical/electronic
- Mechanical
- Operator error

Computer problems
- Problems during download procedure, incorrect parameters
- System parameter reading
- Operator error

Facility problems
- Heat
- Humidity
- Power supply
- Water supply
- Drain

Operator's primary responsibility

- Reagent, calibrator and control preparation and storage
- Sample preparation
- Instrument mechanical alignments and adjustments
- Computer parameters and general computer input/output operations
- Basic component replacement
- Basic operator technique, including computer operation
- Maintenance



The basic operator is not responsible for troubleshooting electrical problems except as covered in this part of the Operator´s Manual: Do not attempt removal of printed circuit boards unless specifically instructed to do so by your local Roche service representative.

When troubleshooting, observe and record the alarms and isolate the problem to the area denoted by the alarms. In many cases, you may be able to find the problem, correct it and then resume processing. The remainder of this chapter provides instructions and guidelines to aid in isolating problems.

Calling Roche service representative

If it becomes necessary to consult Roche service representative to troubleshoot a test or instrument problem, be prepared with the following information:

The items are divided into the following categories:
Chemistry problem on page D-68
Immunoassay problem on page D-69
Instrument problem on page D-69

Chemistry problem

- account number/customer ID number
- instrument serial number
- module type, serial number, and software version
- test(s) affected and other tests on board
- special wash programming
- description of the problem including relevant alarm(s) and alarm code numbers
- catalog number, lot numbers and expiration dates of reagents
- catalog number, lot numbers and expiration dates of calibrators and controls
- lot number of ISE cartridges
- calibration absorbance values from the last few calibrations performed
- control results from the last few controls performed
- patient results (with correlation results, if relevant)
- **Reaction Monitor** report for affected test(s).

Immunoassay problem

- account number/customer ID number
- instrument serial number and software version
- module serial number
- if problem module or channel specific
- one assay or more assays affected and other assays on board
- special wash programming
- description of the problem including relevant alarm(s) and alarm code numbers
- when problem first occurred
- catalog numbers, lot numbers and expiration dates of reagents
- catalog numbers, lot numbers and expiration dates of calibrators and controls
- calibration results from the last few calibrations performed
- control results from the last few controls performed
- patient results (with correlation results, if relevant)

Instrument problem

- account number/customer ID number
- instrument serial number and software version
- description of the problem including relevant alarm(s) and alarm code numbers
- other instrument or maintenance related information.

Instrument troubleshooting

This chapter provides information about troubleshooting procedures for the system as a whole. Procedures for troubleshooting general instrument problems as well as problems during power up are described.

Troubleshooting at Power Up

Conditions that can affect instrument power up are presented in the table below.

To troubleshoot a problem, determine the category below that best describes the problem, and follow the recommended remedy. If all remedies are unsuccessful, call Roche service representative.

PROBLEM: The instrument does not power up when the operation power switch (on the left side of the rack sampler unit) is switched on.

Cause or description	Remedy
1. Instrument is unplugged.	Plug instrument power cord into socket.
2. Main circuit breaker (bottom left of rack sampler unit) in OFF position.	Switch main circuit breaker to the ON position.
3. Module power switch for the **c** 501 or **e** 601 module is switched off.	Switch on the module power switch.
4. The circuit breaker for the instrument power line in your facility is in the OFF position.	Have your facility electrician check the appropriate circuit breaker.
5. Control unit workstation power cable is unplugged.	Plug the power cable into the socket. If the instrument still does not power up, call Roche service representative.

Table D-10 Troubleshooting at power up

General instrument troubleshooting

This section describes the general instrument troubleshooting.

General mechanical problem isolation

The control unit controls and monitors all mechanical functions of the instrument. When a mechanical problem arises within the instrument, it is immediately recognized by the system. The alarm indicator on the global **Alarm** button lights, alerting you to the problem. Touch **Alarm** (global button) to display the **Alarm** screen with the specific alarm code, date and time the alarm occurred and a description of the alarm. Touch a specific alarm to display the alarm details and appropriate remedy.

For certain problems affecting the instrument's performance, the system terminates the operation mode and enters the sampling stop or stop mode. In the sampling stop mode, the system allows completion of the samples in process unaffected by the failure. If the problem affects all samples in process, the computer immediately terminates the operation mode with a stop or emergency stop.



Some instrument problems may arise that the system does not monitor. If this is the case, no alarm will be issued to alert the operator. Such problems may be caused by worn parts, air leaks in the syringe system, reagent contamination, etc. When you encounter these types of problems, you must decide whether to continue to process samples or to terminate the operation, depending on the possibility of causing damage to the system or reporting erroneous test results.

Electrical power not available

If you are having problems powering the analyzer on, follow the procedure below.

► To troubleshoot problems with the electrical power

1 Are the operation ON/OFF switch and circuit breaker switched OFF?

- If yes, then go to step 2.
- If no, then go to step 3.

2 Switch on both power switches.

3 Is the power cable plug disconnected at either the instrument or the outlet?

- If yes, then go to step 4.
- If no, then go to step 5.

4 Firmly connect the power cable.

5 Is the main power outlet working?

- If yes, then go to step 8.
- If no, then go to step 6.

6 Check the circuit breaker in the laboratory distribution box.

7 Ensure line voltage is adequate.

8 If you are still experiencing problems, call Roche service representative.

■

Cannot access another software screen

If you are unable to access another software screen, follow the procedure below.

► To troubleshoot problems accessing another software screen

1. Power OFF the analyzer at the circuit breaker.
2. Check the cabling between the touchscreen and the analyzer.
3. Power ON the analyzer at the circuit breaker. If you are still unable to access another screen, then call Roche service representative.

■

Touchscreen does not come on

If you are having problems with the touchscreen, follow the procedure below.

► To troubleshoot problems with the touchscreen

1. Is the operation ON/OFF switch on the front of the touchscreen switched OFF?
 - If yes, then go to step 2.
 - If no, then go to step 3.
2. Switch the operation switch ON.
3. Is the cable between the touchscreen and the instrument disconnected?
 - If yes, then go to step 4.
 - If no, then go to step 5.
4. Firmly connect the cable.
5. If you are still experiencing problems, call Roche service representative.

■

Touchscreen is difficult to see

If the content of the touchscreen is difficult to see, follow the procedure below.

► To troubleshoot problems with the touchscreen

1. Is the touchscreen dirty?
 - If yes, then go to step 2.
 - If no, then go to step 3.
2. Gently wipe the surface with a dry cloth.
3. Is the ambient lighting too bright?
 - If yes, then go to step 4.
 - If no, then go to step 5.
4. Either reduce the brightness of the ambient lighting or change the direction of the monitor.
5. If you are still experiencing problems, call Roche service representative.

■

Probes do not descend to liquid surface

If the sample probes do not descend to the liquid surface, follow the procedure below.

► To troubleshoot problems with the descending of the probes

1 Are there bubbles on the liquid surface?

- If yes, then go to step 2.
- If no, then go to step 3.

2 Eliminate the bubbles in the sample container with an applicator stick.

3 Did the probe tip touch something during descent? If yes, remove the obstacle.

4 If you are still experiencing problems, call Roche service representative.

■

Bubbles in syringes

If you see bubbles in either the reagent and/or sample syringe, follow the procedure below.

► To troubleshoot problems with bubbles in syringes

1 Perform Reagent Prime (8 on **Maintenance** Items list) from **Utility** > **Maintenance**. From the **ISE** area select **All**, from the **Elecsys** area select the appropriate working solution line (**Reagent** or **Pre-wash Sipper**) and enter 5 cycles.

2 If there are still bubbles in the syringe, repeat this process for the appropriate syringe.

3 If bubbles remain in the syringe after the second pipetter prime, call Roche service representative.

■

c 501 (ISE) troubleshooting

This chapter provides information about troubleshooting procedures specific to the ISE module.

ISE, all results are erratic, excessive air in sipper syringe

For problems with erratic ISE results where there is excessive air in the sipper syringe, follow the procedure below.

► To troubleshoot problems with erratic ISE results and excessive air in the sipper syringe

1. Check reagent volumes in reagent bottles. Are reagent volumes sufficient and is the ISE Ref. reagent line in the solution?

 If not, replace reagent. Make sure the ISE Ref. reagent line is at the bottom of the bottle. Perform an ISE prime of the relevant reagent(s).

2. Is the system leaking?

 If yes, check all tubings and connections for leaks. Tighten loose fittings. Check seals of the ISE and sipper syringes. Choose **Utility** > **Maintenance** and perform *(8) Reagent Prime* on the ISE unit (Ref).

3. Check position of the measuring cartridges. Are measuring cartridges placed properly?

 If no, place cartridge in correct position. Choose **Utility** > **Maintenance** and perform *(8) Reagent Prime* on the ISE unit (Ref).

4. Check reference cartridge placement. Is the reference cartridge placed properly?

 If no, place cartridge in its proper position. Choose **Utility** > **Maintenance** and perform *(8) Reagent Prime* on the ISE unit (Ref).

5. If problem recurs, call Roche service representative.

■

ISE, results are erratic

For problems with erratic ISE results, follow the procedure below.

► To troubleshoot problems with erratic ISE results

1. Is the ISE Ref. reagent line correctly placed in the bottle?

 If no, check line placement, prime reagents and rerun samples.

2. Is there salt buildup on electrodes or syringes or are there any loose connections?

 If yes, tighten any loose or leaky connections, then clean all salt buildup with wet gauze and rerun samples.

3. Check sipper line tubing for kinks or occlusions and remove them.

4. Perform maintenance check *(2) ISE Check*. The Ref. EMF is allowed to be within -7 mV to +7 mV. The maximum deviation for the entire cycle range should be no more than ±2 mV for Ref. EMF. The measurement-to-measurement difference within the 30 cycle interval should not be larger than 0.2 mV for Na, K, and Cl.

 If results are not within range, replace ISE reference cartridge. Choose **Utility** > **Maintenance** and perform *(8) Reagent Prime* on the ISE unit (Ref). Then, recalibrate and rerun samples.

5. Are there air bubbles in the sipper line?

 If yes, call Roche service representative.

6. Verify microbial growth is not present in the reagent system. If necessary, clean the ISE reagent flow path.

 👁 See *Processing green wash rack* on page C-69.

7. If problem recurs, call Roche service representative.

■

ISE, high internal standard values

For problems with high/low ISE internal standard values, follow the procedure below.

► To troubleshoot problems with high/low ISE internal standard values

1 Are the ISE IS EMF value and the ISE IS concentration value higher than normal?

The internal standard EMF deviated ±2 mV maximum from the mean value between the Standard Low and Standard High. The concentration of the internal standard ideally lies at:

Na^+: 140 mmol/L

K^+: 5 mmol/L

Cl^-: 100 mmol/L

- If yes, go to step 2.
- If no, go to step 5.

2 Check that the ISE IS is correctly placed on the system.

Replace ISE reagents if required.

For information about replacing ISE reagents, see:
Figure A-45 on page A-89
c 501 – ISE unit on page B-45

3 Check that fresh ISE calibrators are used and that they are placed in the correct positions of the calibrator rack.

Replace ISE calibrators if required.

4 Check the ISE sipper syringe assembly. Are there leaks?

If yes, call Roche service representative.

5 Perform maintenance check (2) ISE Check. The EMF of the reference electrode must be between -7 mV and +7 mV. The maximum deviation for the entire cycle range should be no more than ±2 mV.

- If all values (Na^+, K^+, and Cl^-) are too high or too low, replace the reference cartridge. An ISE.E data alarm is displayed in the printout adjacent to the respective EMF if the following limits are exceeded:

 Na^+: -90 to -10 mV;

 K^+: -90 to -10 mV

 Cl^-: 80 to 160 mV

- If only single values (Na, K or Cl) are outside the range, replace the respective electrode.

6 If problem recurs, call Roche service representative.

■

ISE, high sodium or low chloride values

For problems with high sodium and low chloride values, follow the procedure below.

► **To troubleshoot problems with high sodium and low chloride values**

1 Were fresh low and high calibrators used?

If no, recalibrate with fresh calibrators and rerun the samples.

2 Prepare fresh ISE IS and ISE Dil. reagents.

- Replace the old ISE IS and ISE Dil. reagents with the fresh reagent.
- Perform a wash: Choose **Utility** > **Maintenance** and perform *(7) Wash Reaction Parts*.
- Prime the fresh reagent: Choose **Utility** > **Maintenance** and perform *(8) Reagent Prime* on the ISE unit (IS).
- Recalibrate two times with fresh ISE IS.
- Rerun the sample.

3 If problem recurs, call Roche service representative.

■

Low ISE values

For problems with low ISE values, follow the steps procedure.

► **To troubleshoot problems with low ISE values**

1 Were fresh low and high calibrators used?

If no, recalibrate with fresh calibrators and rerun the samples.

2 Were fresh ISE reagents used?

If no, prepare fresh ISE IS and ISE Dil.

- Replace the old ISE IS and ISE Dil. reagents with the fresh reagent.
- Perform a wash: Choose **Utility** > **Maintenance** and perform *(7) Wash Reaction Parts*.
- Prime the fresh reagent: Choose **Utility** > **Maintenance** and perform *(8) Reagent Prime* on the ISE unit (IS).
- Recalibrate two times with fresh ISE IS.
- Rerun the sample.

3 Is the correct Std 3 (ISE High) value entered under **Calibration** > **Install** > **Chemistry**?

If no, correct the Std 3 (ISE High) value.

4 If problem recurs, call Roche service representative.

■

c 501 (P) troubleshooting

This chapter provides information about troubleshooting procedures specific to the **c** 501 module.

High test results

The following may cause high test results on the **c** 501 module. Identify which module or modules are giving high test results and troubleshoot according to the procedure below.

► To troubleshoot problems with high test results

1 Incubator bath temperature is incorrect.

- If the bath temperature does not read 37 ±0.1 °C, call Roche service representative.

2 Poor calibration results.

- Check calibrator preparation.
- Check proper calibration programming and calibration results. Repeat calibration if necessary.

3 Calibrators were not properly prepared.

- Check calibrator preparation and calibration results. Repeat calibration.

4 Evaporation of sample or control.

- Repeat analysis with fresh sample and/or control.

 If samples and controls have been loaded on the racks for more than 2 hours, evaporation of sample or control may lead to lower results for patient samples.

5 Reagents were not properly prepared.

- Check reagent preparation and expiration date.

6 Information is not correct **Calibration** > **Install**.

- Verify the calibration points on **Calibration** > **Install** and compare the displayed data with the documentation for a specific test.
- Verify the calibration sample volume in the application parameters.

7 Incorrect sampling or dilution of sample.

- Check correct assembly of sample probe and pipetter parts.
- Check all fittings for leaks.
- Replace O-rings and seals.

8 Insufficient reagent volume.

- Check reagent pipetting system for leaks.
- Replace reagent cassette and repeat analysis.

9 If you are still experiencing problems, call Roche service representative.

■

Low test results

The following may cause low test results on the **c** 501 module. Identify which module or modules are giving low test results and troubleshoot according to the procedure below.

► To troubleshoot problems with low test results

1. Reagents are expired.
 - Prepare new reagents (see instructions for use for stability of the prepared reagent).
2. Reagents were not properly stored.
 - Prepare new reagents (see instructions for use for proper storage).
3. Reagents were not properly prepared.
 - Prepare new reagents (see instructions for use for proper preparation instructions).
4. Incubator bath temperature is incorrect.
 - If the bath temperature does not read 37 ±0.1 °C, call Roche service representative.
5. Evaporation of calibrator.
 - Repeat analysis with fresh calibrator.

 If calibrators have been loaded on the racks for more than 2 hours, evaporation of calibrator may lead to lower results for patient samples.
6. Calibrators were not properly prepared.
 - Check calibrator preparation and repeat the calibration with fresh calibrators.
7. Information is not correct on **Calibration** > **Install**.
 - Check **Calibration** > **Install** and compare the displayed data with the documentation for a specific test.
 - Verify the calibration sample volume in the application parameters.
8. Ensure there is sufficient sample in the container. Check instrument specifications for minimum sample volumes.
9. Check sample for fibrin clotting.
10. Check sample pipetting systems for leaks and air bubbles.
11. Check sample probe for contaminants and obstructions.
12. Repeat analysis with appropriate sample volume.
13. If you are still experiencing problems, call Roche service representative.

■

Erratic test results

The following may cause erratic test results on the **c** 501 module. Identify which module or modules are giving erratic test results and troubleshoot according to the procedure below.

► To troubleshoot problems with erratic test results

1 Fibrin clot in 1 sample container or in sample probe (if low values printed for several samples).

- Check sample for fibrin clot; remove fibrin and repeat analysis.
- Check sample probe for fibrin clot; clean probe (perform maintenance item *(12) Sample Probe Wash*) and perform an air purge.

 👁 See also *Cleaning sample probe, reagent probes, ISE probe and ISE sipper nozzle* on page C-73.
- Replace sample probe and sample probe seal.

2 Sample probe does not reach the bottom of the reaction cell when dispensing sample.

- Perform mechanism check and verify that the probe reaches the bottom of the cell.
- Check the spring mechanism to make sure the probe moves up and down freely.
- The sample probe tip may be damaged. Replace the sample probe.

3 Maintenance was not performed properly or at the recommended frequency on sample or reagent pipetters or probes.

- Check the **Maintenance** screen and perform any overdue maintenance functions.
- If maintenance was recently performed on the sample probe(s), reagent probe(s), rinse nozzles, or any pipetters:
 - Was an air purge performed after maintenance?
 - Were all parts correctly assembled?
 - Have all tubings and seals been checked for air leaks?
 - Were sample and reagent probe seals replaced?

4 Insufficient sample volume.

- Repeat analysis with sufficient sample.

5 Contaminated incubator bath.

- Check for particles in the incubator bath. If particles exist, perform the incubation cleaning procedure

 👁 See *Cleaning the incubator bath* on page C-88.
- Check for foaming, perform incubation water exchange.
- Check for sufficient EcoTergent on the module. Perform incubation water exchange.

6 Check for sufficient volumes of cell cleaning detergents.

7 Check the cell rinse unit for contamination and clean the nozzles if necessary.

👁 For more information, see *Cleaning cell rinse nozzles* on page C-75.

8 If you are still experiencing problems, call Roche service representative.

■

Erratic or biased test results

For problems with erratic or biased test results on **c** 501 module, identify which module or modules are having problems and troubleshoot according to the procedure below.

► To troubleshoot problems with erratic or biased test results

1. Verify that the deionized water supply is free from contamination.
2. Check calibrators used on all modules.
 - Calibrators were not properly prepared. Repeat calibration with fresh calibrator.
 - Check calibrator preparation.
3. Information is not correct on **Calibration** > **Install**.
 - Verify the calibration points on **Calibration** > **Install** and compare the displayed data with the documentation for a specific test.
 - Check that the calibration sample volume in the application parameters is correct.
4. Check sample for fibrin clotting.
5. Ensure there is sufficient sample in the container. Check instrument specifications for minimum sample volumes.
 - Repeat analysis with appropriate sample volume.
6. If you are still experiencing problems, call Roche service representative.

■

Single sample or control

For problems with a single sample or control on the **c** 501 module, identify which module or modules are having problems and troubleshoot according to the procedure below.

► To troubleshoot problems with a single sample or control

1. Verify samples and controls are placed in the proper rack and positions. If necessary, correct the sample or control placement and rerun the sample.
2. Verify the control value ranges and lot numbers entered on **QC** > **Install** are correct. If necessary, correct the control value range or lot number on **QC** > **Install**.
3. Verify the sample and/or control volume is sufficient. Verify the selected sample cup on **Workplace** > **Test Selection**.
4. Verify the sample integrity is acceptable (fibrin, lipemia, hemolysis, icterus). If necessary, collect fresh sample and rerun.
5. Verify the appropriate sample type is selected (serum/plasma, CSF, urine, supernatant, other) and the specimen was collected appropriately. If necessary, correct the sample type; check the instructions for use for acceptable specimen types. Check the specimen collection; check the instructions for use for acceptable specimen collection methods.
6. Verify the collection time and date of the sample are correct. If necessary, collect fresh sample.
7. Verify correct test selections were made on **Workplace** > **Test Selection**. If necessary, correct any selections and rerun the sample.
8. If you are still experiencing problems, call Roche service representative.

■

Single test (1 reagent)

For repeated or consistent problems with a single test on the **c** 501 module, identify which module is having problems and troubleshoot according to the procedure below.

► To troubleshoot problems with a single test (1 reagent)

1. Verify that reagents have not expired, or are not contaminated. If necessary, insert a new reagent cassette.
2. Verify the correct calibrator code and setpoints are used. If necessary, correct the calibrator code and setpoints and repeat the calibration.
3. Verify the special wash programming, if applicable.
4. If you are still experiencing problems, call Roche service representative.

■

Tests with more than 1 calibration point

For problems with tests with more than 1 calibration point on the **c** 501 module, identify which module or modules are having problems and troubleshoot according to the procedure below.

► To troubleshoot problems of tests with more than 1 calibration point

1. Verify calibrators were properly prepared and stored. If necessary, prepare new calibrators and recalibrate.
2. Verify the assigned calibrators are in the correct positions. If necessary, place calibrator(s) in correct position(s), recalibrate and rerun samples. Verify that required diluents are on board.
3. If you are still experiencing problems, call Roche service representative.

■

Multiple photometric tests (more than 1 reagent)

For problems with multiple photometric tests on the **c** 501 module, follow the procedure below.

► To troubleshoot problems with multiple photometric tests (more than 1 reagent)

1. Verify there are sufficient volumes of special wash solutions and detergents. If necessary, replace needed special wash solutions, detergent and rerun samples.
2. Check the reagent probes for barbs, obstructions or leaks.
3. Verify the R1 system is not leaking. Perform an air purge. If the system is leaking, check connections in the R1 probe arm and check connections in the reagent 1 syringe(s).
4. Verify the incubator bath is free of debris and foam. If necessary, perform incubator bath maintenance.
5. Perform a photometer check. Verify the Photometer Check report is within acceptable limits (< 14000). If it is not, replace the photometer lamp. Perform a cell blank. Calibrate all photometric tests.
6. Verify the Reagent 2 probe is aligned properly. If necessary, perform a reagent probe check.
7. Verify the R2 probe system is not leaking. Check connections in the R2 delivery system. Check syringe connections. Perform an air purge.
8. If you are still experiencing problems, call Roche service representative.

■

All photometric tests

For problems with all photometric tests on the **c** 501 module, identify which module or modules are having problems and troubleshoot according to the procedure below.

► To troubleshoot problems with all photometric tests

1. Verify the sample probe is not blocked or does not have barbs at the tip. If necessary, clean the probe. Perform an air purge.
2. Verify the sample system is not leaking. If necessary, check tubings and connections. Perform an air purge and check if there are air bubbles in the syringe.
3. Verify controls/calibrators were properly prepared and stored. If necessary, prepare new controls/calibrators.
4. Check that ultrasonic mixers operate properly.
5. If you are still experiencing problems, call Roche service representative.

■

Biased enzyme results

For problems with biased enzymes on the **c** 501 module, identify which module or modules are having problems and troubleshoot according to the procedure below.

► To troubleshoot problems with biased enzymes

1. Verify the incubator bath level is above the photometer lens.
2. Verify the incubator bath temperature displayed on the **System Overview** screen is 37 ±0.1 °C. Verify there is no *Incubator Bath Temperature* alarm present.

 If the temperature is out of range, perform an incubation water exchange, allow the temperature to stabilize and recheck the bath temperature. If the temperature is still unacceptable, call Roche service representative.
3. Verify controls were prepared using volumetric pipettes. If not, prepare new controls using a volumetric pipette.
4. Perform a full calibration or blank update.
5. Perform a Photometer Check. Verify the **Photometer Check** report is within acceptable limit (< 14000). If not, replace the photometer lamp. Perform a cell blank. Calibrate all photometric tests.
6. Verify the syringe fittings are not loose. If necessary, correct any loose fittings.
7. If you are still experiencing problems, call Roche service representative.

■

e 601 troubleshooting

This chapter provides information about troubleshooting procedures specific to the **e** 601.

Reagent disk cover does not open/close

If you are having problems opening or closing the reagent disk cover, follow the procedure below.

► To troubleshoot problems with opening or closing the reagent disk cover

1. The reagent disk cover is keyed. Is the reagent disk cover properly oriented for placement?
 - If yes, then go to step 3.
 - If no, then go to step 2.
2. Make sure that the reagent disk cover fits into the key before locking.
3. Is there an obstacle around the cover?
 - If yes, then go to step 4.
 - If no, then go to step 5.
4. Remove the obstacle.
5. If you are still experiencing problems, call Roche service representative.

■

Trouble replacing ProCell/CleanCell

If you are having problems replacing a ProCell or CleanCell reagent bottle, follow the procedure below.

► To troubleshoot problems with replacing a ProCell or CleanCell reagent bottle

1. The auxiliary reagent bottles are keyed for proper placement. Are you placing the bottle in its appropriate position?
 - If yes, then go to step 3.
 - If no, then go to step 2.
2. Remove the bottle and check the position before placing the reagent into its proper place.
3. Is there an obstacle beneath the auxiliary reagent bottle?
 - If yes, then go to step 4.
 - If no, then go to step 5.
4. Remove the obstacle.
5. If you are still experiencing problems, call Roche service representative.

■

Trouble replacing PreClean

If you are having problems replacing a PreClean bottle, follow the procedure below.

► **To troubleshoot problems with replacing a PreClean reagent bottle**

1 Ensure PreClean bottles are fully inserted.

2 Ensure the caps have been slightly opened after insertion.

3 If you are still experiencing problems, call Roche service representative.

■

Drift

Control or sample shows drift over a period of time

Possible causes

- Evaporation or incorrect storage conditions of **cobas e** packs.
- **cobas e** packs are not at the proper temperature.
- Recommended calibration frequency not used.
- Recommended handling of controls and/or samples not followed (stability and evaporation).

► **To troubleshoot problems with drift of controls or samples**

1 Have you handled the reagents, calibrators, and/or controls according to the instructions for use?

2 Have you performed recommended maintenance?

3 If you are still experiencing problems, call Roche service representative.

■

Erratic test results

Possible causes

- Foam on sample
- Foam on assay reagents
- Foam on controls
- Not-recommended sample container used

► **To troubleshoot problems with erratic test results**

1 Have you handled the reagents, samples and controls according to instructions for use?

2 Have you performed the recommended maintenance?

3 If you are still experiencing problems, call Roche service representative.

■

Assay calibration

This section describes troubleshooting on assay calibration.

Calibration cannot be performed

Possible causes

- Calibrator vial previously used on the instrument.
- **cobas e** pack or calibrator not on board.
- Missing diluent, for example for CA15-3.
- Calibration not activated in the software.
- Calibrator expiration date exceeded.
- Invalid or unreadable calibrator vial barcode, or calibrator lot specific data not downloaded.
- Data link not available for combination **cobas e** pack and CalSet.
- CalSet 1 and CalSet 2 not on same rack or empty space between CalSets.

► **To troubleshoot problems with calibrations**

1. Check barcode of calibrator vial and **cobas e** pack (barcode damaged?, correct position of the barcode?).
2. Check if calibrator lot specific data has been downloaded.
3. Wipe off the dust on the surface of the barcode reader.
4. Dry the calibrator vial if it is wet.
5. Check calibrator position.
6. If you are still experiencing problems, call Roche service representative.

■

Calibration not released

👁 For more information, see:
Duplicates out of limits on page D-88
Monotony not fulfilled on page D-88
Missing values on page D-88
Values out of limits on page D-89
Calibration factor out of limits on page D-90

Duplicates out of limits

Possible causes Foam on calibrator or assay reagents.

► **To troubleshoot problems with duplicates out of limits**

1. Have you handled the reagents and calibrators according to the instructions for use?
2. Perform a new assay calibration (new CalSet).
3. Have you performed recommended maintenance?
4. If you are still experiencing problems, call Roche service representative.

■

Monotony not fulfilled

Possible causes Calibrators not transferred to the correct barcoded calibrator vials.

► **To troubleshoot monotony problems**

1. Have you handled the reagents and calibrators according to the instructions for use?
2. Perform a new assay calibration (new CalSet).
3. If you are still experiencing problems, call Roche service representative.

■

Missing values

Possible causes
- Empty calibrator.
- Insufficient volume of calibrator or calibrators.

► **To troubleshoot problems with missing values**

1. Have you handled the reagents and calibrators according to the instructions for use?
2. Perform a new assay calibration (new CalSet).
3. If you are still experiencing problems, call Roche service representative.

■

Values out of limits

Values below minimum signal or signal difference between CalSet 1 and CalSet 2 or maximum signal out of limits (latest criteria valid for qualitative assays only).

Possible causes

- Possible causes in connection with reagent handling:
 - **cobas e** pack not at correct temperature.
 - **cobas e** pack not within allowed stability after opening.
 - **cobas e** pack expiration date exceeded.
 - **cobas e** pack stressed (storage or transport conditions not as recommended, for example, temperature, upright position).
 - Foam on assay reagents.
- Possible causes in connection with Calibrator handling:
 - Calibrator not at correct temperature.
 - Foam on calibrator
 - Calibrator handling not as recommended.
 - Calibrator transferred to the incorrect calibrator vial. For example, CalSet 1 transferred to CalSet 2 vial.
 - Calibrators not within allowed stability after opening and/or reconstitution.

► To troubleshoot problems with values out of limits

1. Have you handled the reagents, calibrators, and/or controls according to the instructions for use?
2. Perform a new assay calibration (new **cobas e** pack or new CalSet).
3. Have you performed recommended maintenance?
4. If you are still experiencing problems, call Roche service representative.

■

Calibration factor out of limits

Only valid for quantitative assays.

Possible causes

- Possible causes in connection with reagent handling:
 - **cobas e** pack not at correct temperature.
 - **cobas e** pack not within allowed stability after opening.
 - **cobas e** pack expiration date exceeded.
 - **cobas e** pack stressed (storage or transport conditions not as recommended, for example, temperature, upright position).
 - Foam on assay reagents.
- Possible causes in connection with Calibrator handling:
 - Calibrator not at correct temperature.
 - Foam on calibrator
 - Calibrator handling not as recommended.
 - Calibrator transferred to the incorrect calibrator vial. For example, CalSet 1 transferred to CalSet 2 vial.
 - Calibrators not within allowed stability after opening and/or reconstitution.

► To troubleshoot problems with calibration factor out of limits

1. Have you handled the reagents, calibrators, and/or controls according to the instructions for use?
2. Perform a new assay calibration (new **cobas e** pack or new CalSet).
3. Have you performed recommended maintenance?
4. If you are still experiencing problems, call Roche service representative.

■

Recovery of controls

Control values out of range

Possible causes

- Possible causes in connection with Control handling:
 - Controls not at correct temperature.
 - Control not within allowed stability after opening or reconstitution.
 - Control expiration date exceeded.
 - Foam on controls.
 - Control handling not as recommended.
- Possible causes in connection with reagent handling:
 - **cobas e** packs not at correct temperature.
 - **cobas e** packs not within allowed stability after opening.
 - **cobas e** pack expiration date exceeded.
 - **cobas e** packs stressed (storage or transport conditions not as recommended, for example, temperature, upright position).
 - Foam on assay reagents or auxiliary reagents.
- Possible causes in connection with Calibrator handling:
 - Recommended calibration frequency not followed.

► To troubleshoot problems with control values out of range

1. Have you handled the reagents, calibrators, and/or controls according to the instructions for use?
2. Use another control vial.
3. Perform a new assay calibration (new **cobas e** pack and CalSet).
4. Have you performed recommended maintenance?
5. If you are still experiencing problems, call Roche service representative.

■

Intra assay precision

Intra assay precision out of expected range

Possible causes

- Foam on assay reagents.
- **cobas e** packs and/or sample not at correct temperature.
- **cobas e** packs stressed (storage or transport conditions not as recommended, for example, temperature, upright position).

► To troubleshoot problems with intra assay precision

1. Have you handled the reagents, calibrators, and/or controls according to the instructions for use?
2. Have you performed recommended maintenance?
3. If you are still experiencing problems, call Roche service representative.

■

Inter assay precision (including both channels within 1 module)

Inter assay precision out of expected range

Possible causes

- **cobas e** packs and/or sample not at correct temperature.
- Foam on assay reagents.
- **cobas e** pack stressed (storage or transport conditions not as recommended, for example, temperature, upright position).
- Calibration not carefully carried out.
- Recommended calibration frequency not followed.

► To troubleshoot problems with intra assay precision

1. Have you handled the reagents, calibrators, and/or controls according to the instructions for use?
2. Have you performed recommended maintenance?
3. If you are still experiencing problems, call Roche service representative.

■

Module to module variance

Deviation of control and samples when measured with different modules.

Possible causes

- Recommended handling of assay, auxiliary reagents and calibrators, controls not followed (for example, stability, evaporation).
- Calibration not carefully carried out.

► To troubleshoot problems with the module to module variance

1. Have you handled the reagents, auxiliary reagents, calibrators, and/or controls according to the instructions for use?
2. Have you performed recommended maintenance?
3. If you are still experiencing problems, call Roche service representative.

■

Method comparison

Deviation of method comparison when compared with competitors (internal, external)

Possible causes

- Different standardizations (reference material).
- Different antibodies (for example, HCG on Elecsys/ES).
- Different methods (RIA/ELISA etc.).
- Different units (conversion factor between units sometimes different from competitor to competitor).
- Different sample material +/- anticoagulants.
- Recommended calibration frequency not followed.
- Calibration handling not as recommended.
- The number of samples is too small, and/or all results are within a very limited range compared to the measuring range of the assay.
- Reagent lot to reagent lot variance.
- System to system variance.

► To troubleshoot problems with the method comparison

1. Have you handled the reagents and calibrators according to the instructions for use?
2. Have you performed recommended maintenance?
3. If you are still experiencing problems, call Roche service representative.

■

Software description E

21 System overview E-3
22 Global screens E-49
23 Workplace menu E-201
24 Reagent menu E-249
25 Calibration menu E-265
26 QC menu E-309
27 Utility menu E-355

System overview

The **System Overview** screen is the central screen used for performing daily operation. From here you can view the status of all modules, check the amount of consumables available and perform all steps that are necessary for daily operation.

In this chapter *Chapter* 21

System Overview screen E-5
Work Flow Guide area E-6
Module Overview area E-8
Module button section E-8
Text field section E-8
Buttons E-9
Main menu buttons area E-10
Sample Data Clear window E-11
Reagent Preparing window E-12
Calibration and QC Select window E-13
Calibration area E-14
QC area E-14
Load List area E-15
To Do List window E-16
Sample Tracking window E-17
Tray 1 tab E-18
Rack Monitor area E-18
Rack Information area E-19
Position Status area E-20
Others tab E-21
Rack Monitor area E-21
Sample Search area E-21
Rack Information area E-22
Position Status area E-23
Buttons E-23
Sample Search window E-24
Stat and Routine tab E-24
Unload tab E-25
Type area E-25
Status area E-25

Backup Operation window (c 501 module) E-26
Buttons E-26
Reagent Overview window (c 501 module) E-27
Reagent area E-28
Inventory area E-30
ISE area E-30
Buttons E-31
Reagent Overview window (e 601 module) E-32
Reagent area E-33
Inventory area E-35
Buttons E-36
Detail window E-37
Assay cobas c pack E-37
Diluent cobas c pack E-39
Wash solution cobas c pack E-40
Assay cobas e pack E-41
Pretreatment cobas e pack E-43
Diluent cobas e pack E-45
Inventory Update window E-47
Temperature window (e 601 module) E-48

System Overview screen

The **System Overview** screen is automatically displayed after log on.

➔ Choose the graphical icon representing the configuration in the status line (top left of the screen).

➔ Press <F12>.

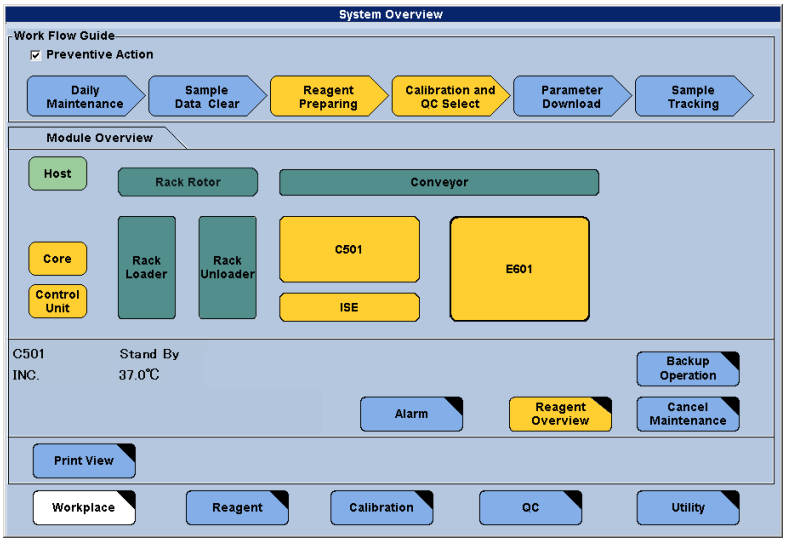


Figure E-1 System Overview screen

The **System Overview** screen has a central role within the **cobas** 6000 analyzer series software. From here the user has an overview of the whole system at any time. It displays the status of each completed sample, and the modules can be prepared for daily routine operation (via **Work Flow Guide**).

For more information, see *Overview* on page B-29.

The **System Overview** screen is divided into the following areas:

- Work Flow Guide area
- Module Overview area
- Main menu buttons area

For information on the global buttons (e.g. **Stop**, **Shut Down**, **S.Stop**, etc.), see *Global buttons* on page E-56.

Work Flow Guide area

The **Work Flow Guide** area guides the user through the daily routine. This area consists of 6 buttons, the colors vary depending on their status. By choosing these buttons, screens and windows are displayed that enable the user to take actions appropriate to the situation.

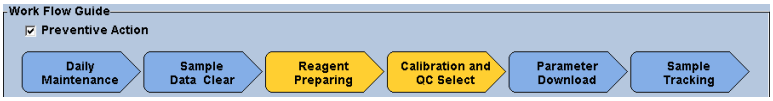


Figure E-2 Work Flow Guide area

The **Work Flow Guide** area uses a color scheme to display the status of the system. The color scheme is different when preventive action is activated (the **Preventive Action** check box is selected). A table describes the meaning of the color scheme for each button of the **Work Flow Guide**.

See *Colors in the Work Flow Guide* on page B-38.

Preventive Action

Preventive action is a prediction of at what might be required during the daily routine. When activated, preventive action triggers the following items:

- Reagent purple alarm (diluent, test reagent or detergent volume is less than the daily requirement).
- Recommended calibration for tests with calibrations due within the **Remaining Time** set on the **Calibration Status** screen.

At wake up or power on, the **Preventive Action** check box on the **System Overview** screen is automatically selected and therefore active.

It is recommended to deselect the **Preventive Action** check box after all recommended reagents are loaded and recommended calibrations are performed.

Recommended calibrations are only performed if they were confirmed and accepted by the operator.

The values for *Purple Alarm* are defined in **Utility** > **System** > (**Page 2/4**) > **Reagent Level Check** window under **Purple Alarm**.

The time intervall for the Calib. Now function is entered on the **Calibration** > **Status** screen.

Daily Maintenance

Use the **Maintenance** button to execute maintenance actions or maintenance pipe functions. Choosing **Maintenance** displays the **Utility** > **Maintenance** screen.

See *Maintenance screen* on page E-420.

Daily maintenance items programmed as a maintenance pipe can be defined as a power up pipe and will be performed automatically when the system powers on.

Sample Data Clear

The **Sample Data Clear** button can turn yellow or red. It turns yellow when the database (**Routine View** on **Workplace** > **Data Review** screen) is nearly full (9,400 sample data) and red when it is full (10,000 sample data). When the **Sample Data Clear** button is yellow it is recommended that the operator deletes the results. When it is red, patient samples are no longer processed.

See *Sample Data Clear window* on page E-11.

Reagent Preparing

Choose this button to display the **Reagent Preparing** window. Use the **Reagent Load List** button to provide a list of reagents that need to be loaded on to the modules in order to carry out the daily routine. Use this button to print a **Reagent Load/Unload List** after confirmation.

See *Reagent Preparing window* on page E-12.

Use the **Reagent Prime** button to display the **Reagent Prime** window in the **Utility** >**Maintenance** menu. Use this window to perform a reagent prime.

See *Reagent Prime window* on page E-256.

Calibration and QC Select

This button is yellow when a calibration or control needs to be performed.

Choose this button to display the **Calibration and QC Select** window. Use this window to select the type of calibration and QC you wish to perform and to print **Calibration** and **QC Load Lists**.

See *Calibration and QC Select window* on page E-13.

Parameter Download

Choose this button to display the **To Do List** window.

Red indicates that a **cobas c** pack, **cobas e** pack, calibrator, or QC was loaded onto the analyzer, which has not been installed before. New information for applications, controls, and calibrators must be downloaded from **cobas** link.

See *To Do List window* on page E-16.

Sample Tracking

Sample Tracking allows the operator to search for any sample on the analyzer (as soon as it is registered by the analyzer) and provides an overview of the samples in the unloader.

Choose this button to display the **Sample Tracking** window.

See *Sample Tracking window* on page E-17.

Module Overview area

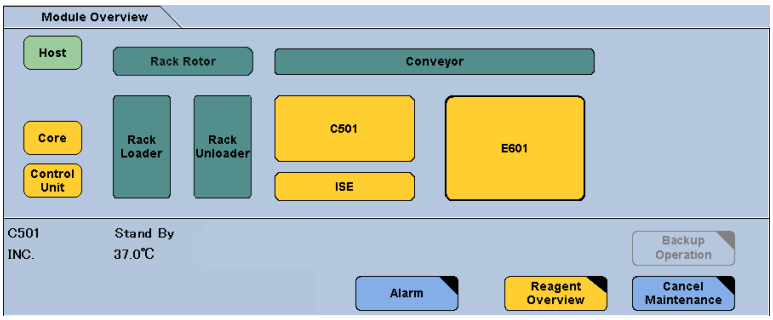


Figure E-3 Module Overview area

The **Module Overview** area provides a view of the current status of the modules and components (for example, **Host**, **Core**, **ISE, c** 501, **e** 601, **Rack Loader**) of the **cobas** 6000 analyzer series system. The **Module Overview** area uses a color scheme to display the status of the system. From here, the user can also access the **Temperature** window (**e** 601 module only), **Alarm** screen and **Reagent Overview** windows by choosing the corresponding button.

The **Module Overview** area consists of 2 sections: the module button section and the text field section.

Module button section

The module button section contains buttons corresponding to all the modules and components of the system. These buttons display different colors depending on the status of the module or component. If more than one color applies, the color with the highest priority is displayed.

The color scheme is different when preventive action is activated (the **Preventive Action** check box is selected).

See *Colors in the Module Overview* on page B-39.

By choosing a particular module or component button, more details (e.g., status) are displayed in the text field.

Text field section

The text field section, the lower section, displays information relevant to the module or component currently selected and their corresponding buttons, for example, temperatures.

On the left of the text field, the name and status of the module or component are displayed (e.g., **Stand By**).

Buttons

On the right of the text field are the shortcut buttons. A shortcut button to the **Alarm** screen is available for all modules and components. When a module is selected, **Backup Operation** (**c** 501 module only), **Temperature** (**e** 601 module only), **Reagent Overview**, and **Cancel Maintenance** buttons are also available.

*Backup Operation (**c** 501)* Use this button to display the **Backup Operation** window. In backup operation mode, sample racks can be processed on a **c** 501 module even in case of troubles with the rack sampler unit.

See *Backup Operation window (c 501 module)* on page E-26.

Alarm This button displays the color corresponding to the highest priority alarm of the currently selected module or component.

Use this button to display the global **Alarm** screen. The alarms correspond to the module or component currently selected.

See *Alarm screen* on page E-65.

Reagent Overview This button displays the color corresponding to the highest priority status of the module currently selected.

Choose this button to display the **Reagent Overview** window. This window displays an overview of the reagents loaded on the module currently selected.

For more information, see:
Reagent Overview window (c 501 module) on page E-27
Reagent Overview window (e 601 module) on page E-32

Cancel Maintenance Use this button to force all maintenance items running on the currently selected module to stop after confirmation.

Some maintenance items performed on the **c** 501 (P) cannot be stopped once they have started.

*Temperature (**e** 601)* Choose this button to display the **Temperature** window. This window displays actual, target and control temperatures for the module currently selected.

See *Temperature window (e 601 module)* on page E-48.

Print View Use this button to display the **Print View** window. This window is used to view reports in the print buffer, to print and also to write reports to a disk.

See *Print View window* on page E-70.

Main menu buttons area



Figure E-4 Main menu buttons area

The main menu buttons provide access to the screens of the main menu.

Workplace Use the **Workplace** menu to make test selections, specify patient demographics, assign patient IDs and rack positions to samples. Use this button to review, backup, edit, delete and send data to the Host.

For more information, see *Workplace menu* on page E-201.

If the system is connected to a Host, test selections, patient demographics and patient IDs can be specified by the Host.

Reagent Use the **Reagent** menu to view detailed reagent information and to manage the reagents of the analyzer.

For more information, see *Reagent menu* on page E-249.

Calibration Use the **Calibration** menu to request calibrations, define calibrators and view the calibration results.

For more information, see *Calibration menu* on page E-265.

QC Use **QC** menu to install, view and edit controls, and to manage quality control results.

For more information, see *QC menu* on page E-309.

Utility Use the **Utility** menu to enter system parameters, application parameters, maintenance settings and system settings.

For more information, see *Utility menu* on page E-355.

Sample Data Clear window

➔ **System Overview** > **Sample Data Clear**

Choose **Sample Data Clear** when the button is red or yellow to display the **Sample Data Clear** window.

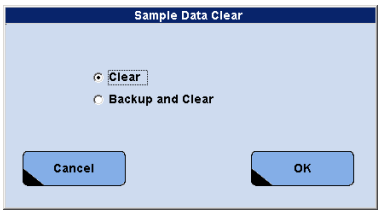


Figure E-5 Sample Data Clear window

Use the **Sample Data Clear** button to delete the sample results. If **Sample Data Clear** is executed, all records of the samples are deleted and QC data is moved to the QC view. Less sample data in the database allows faster access to the data. Backing up on a periodic basis is recommended. If your system is connected to a Host, make sure that all data has been uploaded before performing the Sample Data Clear.

See *Archiving patient data* on page B-91.

Clear Select the **Clear** option and choose **OK** to clear the database without saving any data after confirmation.

Back Up and Clear Select the **Back Up and Clear** option and choose **OK** to back up the data stored in the database before it is cleared. The **Back Up Data** window is displayed.

See *Backup Data window* on page E-230.

Reagent Preparing window

➔ **System Overview** > **Reagent Preparing**

Choose **Reagent Preparing** when the button is red, yellow or purple to display the **Reagent Preparing** window.

See *Color scheme of the System Overview screen* on page B-37.

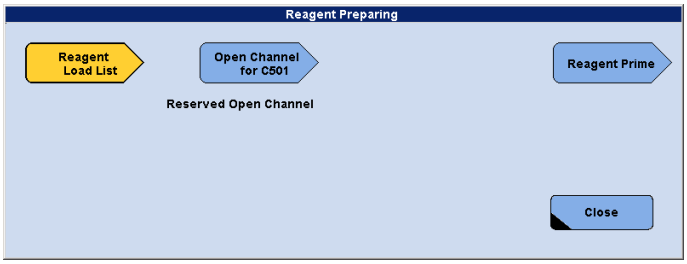


Figure E-6 Reagent Preparing window

Use this window to print a **Reagent Load/Unload** List. This window is also used to assign a **cobas c** pack MULTI to a development channel application (Open Channel for **c** 501) or to perform a reagent prime.

Reagent Load List

The **Reagent Load/Unload** List displays the **cobas c** packs, **cobas e** packs and auxiliary reagents that need to be loaded onto the analyzer in order to carry out the daily routine. Use this button to print a **Reagent Load/Unload** List after confirmation.

Replace any required reagent, diluent, and auxiliary reagent according to the **Reagent Load/Unload** List. Ensure that reagents have not exceeded their expiration dates.

See *Reagent Load/Unload List* on page E-104.

*Open Channel for **c** 501*

Use this button to assign a **cobas c** pack MULTI to a previously installed development channel application (open channel). This must be done before loading the corresponding **cobas c** pack MULTI.

See *Open Channel window* on page E-258.

Reagent Prime

This button displays the **Reagent Prime** window in the **Utility** > **Maintenance** menu. Use this window to perform a reagent prime.

See *Reagent Prime window* on page E-256.

Calibration and QC Select window

➔ **System Overview** > **Calibration and QC Select**

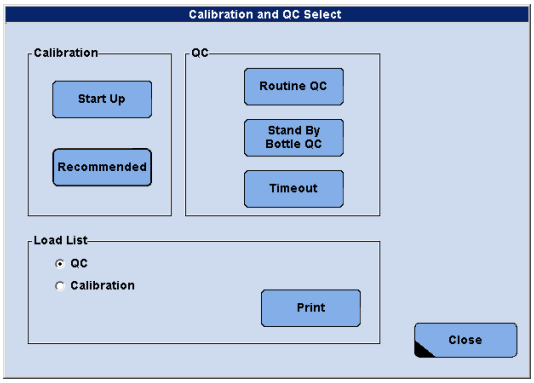


Figure E-7 Calibration and QC Select window

Use this window to select the type of calibration and quality control to be performed after a calibration or QC warning has been issued.

For more information, see:
Calibration and QC Select button on page B-51
To request calibration and QC on page B-53

Roche recommends to perform QC measurement at least once every 24 hours.

The **Calibration and QC Select** button on the **System Overview** screen turns yellow indicating a warning has been issued which can be due to the following:

- The system has recommended a calibration or QC measurement.
- A calibration or QC measurement has failed the validation criteria.

The load lists for calibrators, controls or both can also be printed from this screen.

Choose **Calibration and QC Select** on the **Work Flow Guide** area of the **System Overview** screen to display this window.

See *Calibration and QC Select button* on page B-51.

The **Calibration and QC Select** button is yellow if the system recommends a calibration or control to be measured.

The **Calibration and QC Select** window is divided into 3 areas:

- Calibration area
- QC area
- Load List area

Calibration area

When a calibration is required, use this area to select the type of calibration to be performed.

Start up Choose this button to select all tests predefined as a Start Up calibration in the **Calibration** > **Status** > **Start Up Setting** window.

Recommended Choose this button to select the test(s) recommended for calibration by the system.

This button turns yellow due to the following reasons:

- Changeover
- Timeout
- Failed
- QC violation
- Calib. Now

For more information, see:
Causes for automatic calibration recommendations on page B-156
Calibration > *Status* on page E-267

QC area

When a control is required, select the method of control to be performed from this area.

For information about applying QC rules, refer to the COBI CD.

Routine QC **Routine QC** performs controls for all activated tests of all installed controls. Choose this button to order the routine QC. Routine controls are defined on the **Status** screen of the **QC** menu.

See *Routine QC window* on page E-313.

Stand By Bottle QC **Stand By Bottle QC** performs controls for all standby **cobas c** packs and **cobas e** packs.

Timeout Timeout QC performs controls for all tests whose QC interval has been exceeded (defined on the **Utility** > **Application** > **Range**). The button turns yellow. Choose this button to perform the Timeout QC.

For more information, see *Description of application parameters – Range tab* on page B-267.

Load List area

After selecting the calibration and QC to be processed, load lists can be used as an aid when loading the required controls and/or calibrators on to the Rack Loader. Use this area to select the type of load list to be printed. There are two options: **Calibration** or **QC**. Select an option and choose **Print** to print a **Calibration** or **QC Load List**.

See *Reports* on page E-75.

QC Choose the **QC** option to print a load list for controls recommended by the system.

Calibration Choose the **Calibration** option to print a load list for calibrators recommended by the system.

Print Choose this button to initiate printing of the selected load list.

To Do List window

➔ **System Overview** > **Parameter Download**

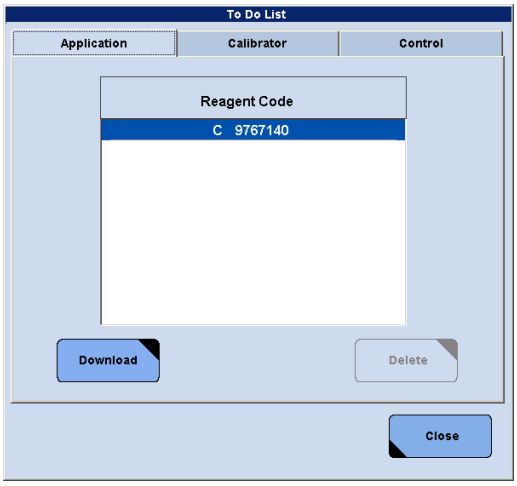


Figure E-8 To Do List window

Choose **Parameter Download** when the button is red to open the **To Do List** window.

The **Parameter Download** button turns red to signal that some information is missing that must be downloaded from **cobas** link. For example if a calibrator barcode is read by the barcode reader and calibrator data of this lot has not been downloaded.

For an overview of downloading parameters from **cobas** link, see *Installing an application* on page B-252.

Download Use this button to display the appropriate screen. Depending on the tab that was selected on the **To Do List** window, one of the following screens is displayed:

- **Utility** > **Application**
- **Calibration** > **Install**
- **QC** > **Install**.

On each of these screens, you can initiate the download of the missing item from **cobas** link by choosing the **Download** button.

See *Download window* on page E-348.

Delete Choose this button to delete the selected item from the **To Do List** window. The button turns blue after deleting all items.

Sample Tracking window

➔ **System Overview** > **Sample Tracking**

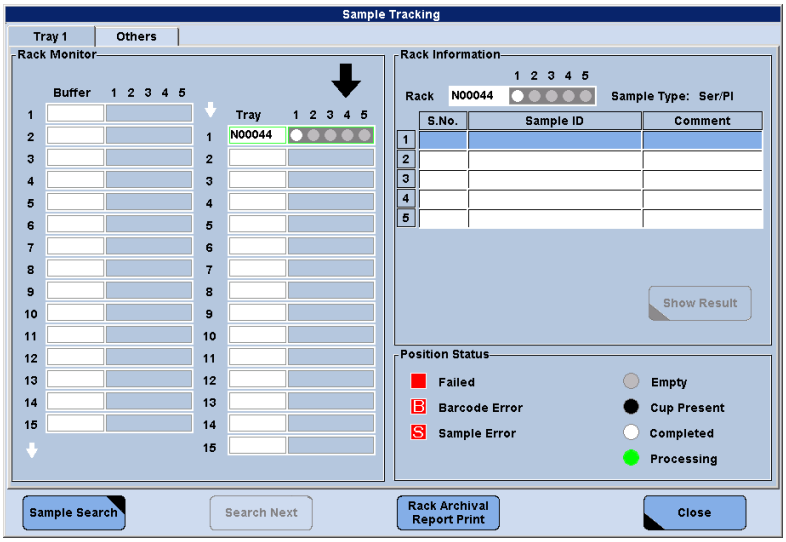


Figure E-9 Sample Tracking window - Tray view

The **Sample Tracking** window allows the operator to search for any sample on the analyzer from the moment of registration (the sample has passed the barcode reader) to the moment when the sample reaches the rack unloader (Tray 1).

The **Sample Tracking** window also allows the operator to search for samples and subsequently unload them.

The **Sample Tracking** window has 2 tabs:

- Tray 1 tab (Tray 1 = rack unloader)

 Provides detailed information on the samples in the unloader.

- Others tab

 Provides detailed information on a sample that is already registered by the analyzer (has passed the barcode reader) but has not yet reached the unloader.

 Allows the operator to search for samples on the analyzer to be unloaded.

For more information, see:
Sample tracking on page B-70
Tracking samples on the analyzer on page B-98
To unload specific racks on page B-100

Control and calibrator information is not displayed on the **Sample Tracking** window.

Tray 1 tab

This tab provides detailed information on the samples in the rack unloader.

For more information, see *Rack loader/unloader* on page A-54.

The **Tray** tab consists of the following areas:

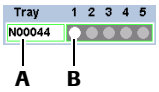
- Rack Monitor area
- Rack Information area
- Position Status area

Rack Monitor area

This area visualizes the racks and samples in the rack unloader.

The rack unloader can take in up to 30 racks. 15 racks in the *Buffer* tray and 15 racks in the *Tray* in the front of the unloader rack. The currently selected rack is marked with a green border.

For each rack the following information is displayed:



A Rack number
B Status of the sample

Figure E-10 Sample Tracking window - A rack in the Rack Monitor area

Rack number The first column displays the rack number, for example, N00001. The first character can be any of the following:

N	=	Normal/routine (gray rack)
E	=	Emergency/STAT (red rack)
R	=	Rerun (pink rack)
C	=	Control (white rack)
S	=	Standard (black rack)
B	=	Green rack (wash)
?	=	Rack not processed due to a rack ID read error.

Status of the sample The graphical display to the right of each rack number shows the status of the sample (1 to 5) in each rack. A legend of symbols and colors is displayed in the **Position Status** area in the lower right corner of the **Sample Tracking** window.

See *Position Status area* on page E-20.

The rack ID printed on the rack is different to the ID shown on the screen. For example, Rack: Q110 / Screen C00110.

See *Sample racks* on page A-59.

Rack Information area

This area displays detailed information about each sample of the rack currently selected in the **Rack Monitor** area.

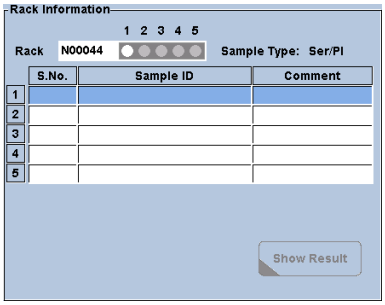
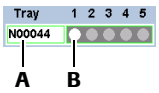


Figure E-11 Rack Information area

Control and calibrator information is not displayed on the **Sample Tracking** window.

Rack This field displays the rack selected in the **Rack Monitor** area:



A Rack number
B Status of the sample

Figure E-12 Sample Tracking window - A rack in the Rack Information area

On the left (**A**), the rack number is displayed, for example, N00001. On the right (**B**) the status of each sample in the rack is displayed.

See *Rack Monitor area* on page E-18.

A legend of symbols and colors is displayed in the **Position Status** area in the lower right corner of the **Sample Tracking** window.

See *Position Status area* on page E-20.

Sample Type This field displays the sample type of the rack.

S. No. (non-barcode mode) The **S. No.** column displays the sequence number that identifies the sample (non-barcode mode).

Sample ID The **Sample ID** column displays the identification of the sample.

Comment The **Comment** column displays the text entered in the **Main Comment** field on the **Demographics** windows.

For more information, see:
Demographics window on page E-211
.*Comment Title window* on page E-383.

Show Result Use this button to display the **Workplace** > **Data Review** screen and to view the result of the selected sample.

See *Data Review screen* on page E-216.

Position Status area

The **Position Status** area displays a legend that defines the symbols and colors used in the **Sample Tracking** window.

The following table explains the symbols of the **Position Status** area:

	**Failed**	Measurement is completed and one or more results have a data alarm, or a test could not be processed.
	**Barcode Error**	The barcode is unreadable (displayed in barcode mode only).
	**Sample Error**	Possible reasons for sample error are: • Sample short • Air bubbles (only for e-module) • Sample clot
	**Empty**	The selected rack position is empty.
	**Cup Present**	A cup is present but no request has been made.
	**Completed**	The sample is completed with no flags.
	**Processing**	The sample is being processed.

Others tab

This tab is used to search for a sample that is being processed on the analyzer. It provides detailed information on a sample that is already registered by the analyzer (has passed the barcode reader) but has not reached the unloader yet.

Use the **Sample Search** window to search for a specific sample.

See *Sample Search window* on page E-24.

This function is only available in Operation mode.

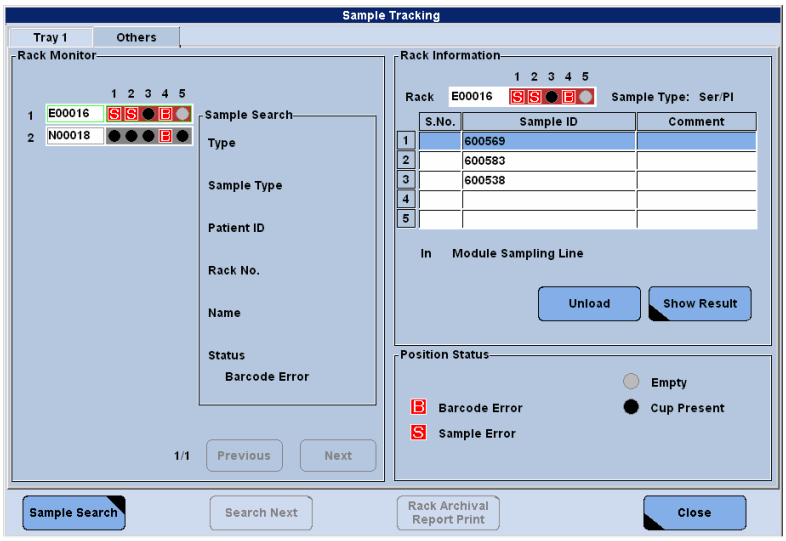


Figure E-13 Sample Tracking window - Others view

The **Others** tab consists of the following areas:

- Rack Monitor area
- Rack Information area
- Position Status area

Rack Monitor area

This area shows the racks that were found using the sample search function. The search criteria selected on the **Sample Search** window are shown in the **Sample Search** area.

Sample Search area

This area displays the search criteria selected on the **Sample Search** window. The racks that were found using the sample search function are shown in the **Rack Monitor** area.

If any criteria are not defined on the **Sample Search** window, the corresponding field below the criterion is left blank.

Type This field displays the search criterion for the rack type, for example, *Routine*.

Sample Type This field displays the search criterion for the sample type, for example, *Ser/Pl*.

Sequence No. (non-barcode mode) This field displays the search criterion for the sequence number.

Patient ID (barcode mode) This field displays the search criterion for the patient ID.

Rack No. This field displays the search criterion for the rack number.

Comment This field displays the search criterion for the main comment.

See *Comment Title window* on page E-383.

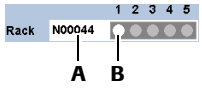
Status This field displays the search criterion for the sample status, for example, *Sample Error*.

Rack Information area

This area displays detailed information about each sample of the rack containing the sample that was searched using the **Sample Search** window.

Control and calibrator information is not displayed on the **Sample Tracking** window.

Rack This field displays the rack that contains the selected sample.



A Rack number
B Status of the sample

Figure E-14 Sample Tracking window - A rack in the Rack Information area

On the left (**A**), the rack number is displayed, for example, N00001. On the right (**B**) the status of each sample in the rack is displayed.

See *Rack Monitor area* on page E-18.

A legend of symbols and colors is displayed in the **Position Status** area in the lower right corner of the **Sample Tracking** window.

See *Position Status area* on page E-20.

Sample Type This field displays the sample type of the rack.

S. No. (non-barcode mode) The **S.No.** column displays the sequence number that identifies the sample.

Sample ID The **Sample ID** column displays the identification of the sample.

Comment The **Comment** column displays the text entered in the **Main Comment** field on the **Demographics** windows.

For more information, see:
Demographics window on page E-211
Comment Title window on page E-383

In This field displays a short message indicating the location of the sample, for example, *In Rack Rotor...*

Unload Use this button to unload the racks selected in the **Rack Information** area.

See *To unload specific racks* on page B-100.

Show Result Use this button to display the **Workplace** > **Data Review** screen and to view the result of the selected sample.

See *Data Review screen* on page E-216.

Position Status area

The **Position Status** area displays a legend that defines the symbols and colors used in the **Sample Tracking** window.

In the **Others** tab the status *Cup present* is used instead of *Processing*, *Complete* or *Failed*.

See *Position Status area* on page E-20.

Buttons

Sample Search Use this button to search the database for information on a STAT or Routine sample. Choose this button to display the **Sample Search** window.

See *Sample Search window* on page E-24.

Search Next Choose this button to repeat the search for the next valid sample that meets the search criteria. This button is enabled after specifying search criteria on the **Sample Search** window.

Rack Archival Report Print Choose this button to print the **Rack Archival** report. This report lists the racks and the corresponding samples which were processed.

See *Rack Archival Report* on page E-175.

Sample Search window

➔ **System Overview** > **Sample Tracking** > **Sample Search**

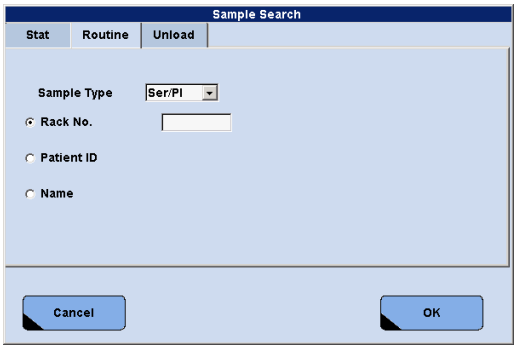


Figure E-15 Sample Search Routine window

Use this window to search for a specific sample using specified criteria. The **Sample Search** window has 3 tabs:

- **Stat**: Use this tab to search for specific STAT samples.
- **Routine**: Use this tab to search for specific routine samples.
- **Unload**: Use this tab to search for specific routine or STAT samples to be unloaded.

Stat and Routine tab

Sample Type Use this list box to specify the sample type to be used as a search criterion (for example, **Ser/Pl**, **Urine**, **CSF**).

Rack No. Select this option to enable a text box in which to enter a rack number as a search criterion.

Sequence No. (non-barcode mode) Select this option to enable a text box in which to enter a sequence number as a search criterion.

Patient ID (barcode mode) Select this option to enable a text box in which to enter a patient ID number as a search criterion.

Main Comment field Samples can be searched for by the information entered in the **Main Comment** field (for example *Name*) on the **Demographics** windows.

Select this option to enable a text box. Type the comment text that you are searching for. You do not have to enter the complete search text.

👁 For more information, see:
Demographics window on page E-211
Comment Title window on page E-383

Unload tab

The **Unload** tab can be used to search for specific routine or STAT samples to be unloaded. A list of racks that meet the search criteria is displayed in the **Rack Monitor** area of the **Sample Tracking > Others** window.

The **Unload** tab offers two main search criteria:

- **Type**
- **Status**

For more information, see *To unload specific racks* on page B-100.

Type area

Select the **Type** option to activate the search criteria of the **Type** area.

Type list box Use the list box in the header of the type area to specify the rack type (**Routine** or **STAT**) to be used as a search criterion.

Sample Type Use this list box to specify the sample type to be used as a search criterion (for example, **Ser/Pl**, **Urine**, **CSF**).

Sequence No. (non-barcode mode) Select the **Sequence No.** option to enable a text box in which to enter a sequence number as a search criterion.

Patient ID (barcode mode) Select the **Patient ID** option to enable a text box in which to enter a patient ID number as a search criterion.

Rack No. Select the **Rack No.** option to enable a text box in which to enter a rack number as a search criterion.

Main Comment field Select the **Main Comment** option to enable a text box. Type the comment text that you are searching for. You do not have to enter the complete search text.

Samples can be searched for by the information entered in the **Main Comment** field (for example *Name*) on the **Demographics** windows.

For more information on the **Main Comment** field, see:
Demographics window on page E-211
Comment Title window on page E-383

Status area

Select the **Status** option to activate the search criteria of the **Status** area.

Status list box Use this list box to specify the sample status to be used as a search criterion. Possible statuses are: **Completed**, **Failed**, **Barcode Error**, **Sample Error**.

Backup Operation window (c 501 module)

➔ **System Overview** > select **c** 501 module > **Backup Operation**

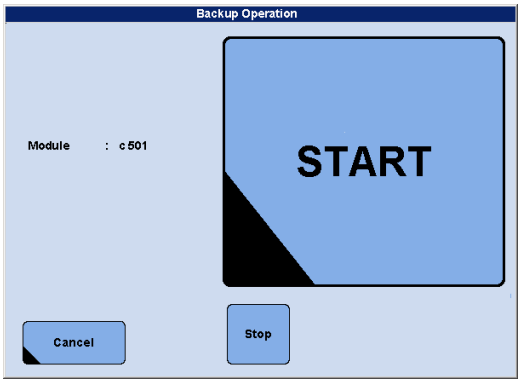


Figure E-16 Backup Operation window (**c** 501 module)

Use this window to start the backup operation mode. In backup operation mode, sample racks can be processed on a **c** 501 module even if the rack sampler unit is not functioning.

In backup operation mode, only routine and STAT samples can be processed (including rerun samples).

For information on measuring samples in backup operation mode, see *Backup operation* on page B-240.

Buttons

Start Use this button to start backup operation. When the instrument goes into *Backup Wait For Rack Setting* status, place a sample rack into the backup operation port. Make sure that the rack is positioned as shown on the label.

Stop Use this button to terminate backup operation after all samples have been processed.

Reagent Overview window (c 501 module)

➔ **System Overview** > select a **c** 501 module > **Reagent Overview**

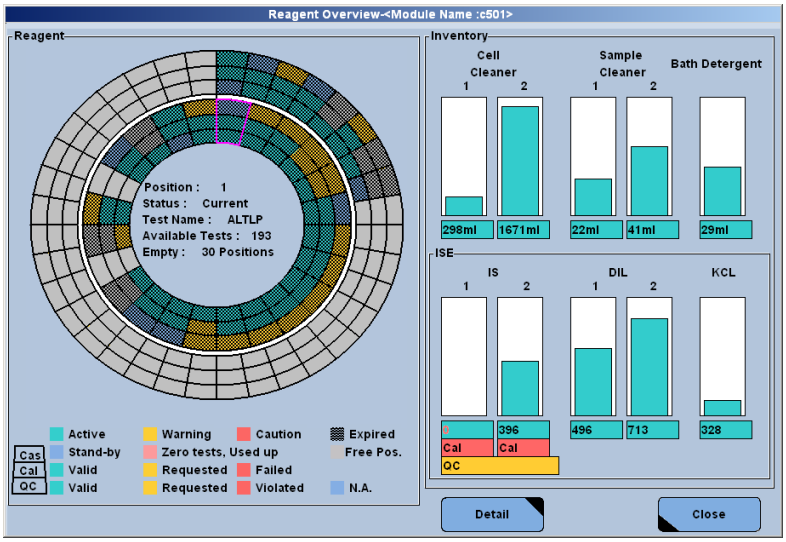


Figure E-17 Reagent Overview window (**c** 501 module)

Use this window to view the status of the reagents (**cobas c** packs, ISE reagents and auxiliary reagents) loaded on the selected module.

This window is divided into 3 areas:

- **Reagent** area, displays the status of each **cobas c** pack
- **Inventory** area, indicates the status and the level of the auxiliary reagents
 See *Auxiliary reagents* on page B-111.
- **ISE** area, indicates the status and the level of the ISE reagents
 See *Reagents for ISE applications* on page B-105.

Reagent area

Use this area to view the status of the **cobas c** packs, loaded on the module. This area comprises a graphic representing the reagent disk and a legend.

The graphic is divided into 2 large rings. Each of the large rings is subdivided into 3 subrings. The 24 segments of the inner large ring and the 36 segments of the outer large ring represent the 60 **cobas c** packs positions within the reagent compartment.

Each segment shows the following information:



- **Cas**: Reagent status (inner subring)
- **Cal**: Calibration status (middle subring)
- **QC**: QC status (outer subring)

Choosing a segment displays in the center of the graphic detailed information about the **cobas c** pack.

Legend

The legend at the bottom of the **Reagent** area explains the colors represented in the segments of the reagent disk graphic.

1. Inner subring: Cas (Cassette = **cobas c** pack)

	Active	This **cobas c** pack is currently in use.
	Warning	Remaining tests in this **cobas c** pack set below yellow alarm level (**Utility** > **System** (**Page 2/4**) > **Reagent Level Check**).
	Caution	There is no reagent available for this assay on this module.
	Stand-by	This **cobas c** pack is currently not in use.[(a)]
	Zero tests, Used up	The **cobas c** pack has been used up and is empty. There is still reagent available in another **cobas c** pack on this module.
	Free Pos.	There is no **cobas c** pack in this channel.
	Expired	The **cobas c** pack has exceeded its expiration date.

(a) Standby **cobas c** packs are already on board but not currently in use.

2. Middle subring: Cal (Calibration)

	Valid	A valid calibration is available.
	Requested	A calibration has been requested.
	Failed	The calibration of the **cobas c** pack has failed.

3. Outer subring: QC (Quality Control)

Valid	QC result is within the confidence limits.
Requested	A QC has been requested.
Violated	QC result is not within the confidence limits.
N.A.	Not applicable.

For diluent and cleaner **cobas c** packs, only the inner subring (**Cas**) contains information.

Reagent information

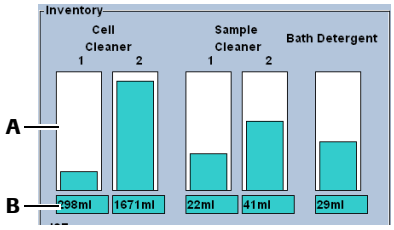
Information about the selected **cobas c** pack is displayed in the center of the reagent disk.

The following information is provided:

Position	Position of the **cobas c** pack in the reagent disk.
Status	Indicates that the **cobas c** pack is active or standby.
Test Name	Name of the **cobas c** pack.
Available Tests	Indicates the total number of determinations that can be measured with the currently available **cobas c** packs (including the standby **cobas c** packs). If a **cobas c** pack contains diluent or cleaner, the total volume is displayed in ml.
Empty	Number of empty positions on the reagent disk.

Inventory area

The **Inventory** area displays the amount of auxiliary reagents on the selected module on the **System Overview** screen.



A Bar chart for the remaining volume

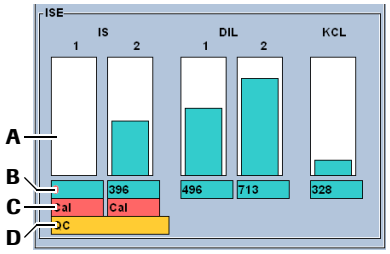
B Color-coded bar

Figure E-18 Inventory area of Reagent Overview window

Auxiliary reagent	Unit	Color	Description
Cell Cleaner 1/2	ml	Yellow	Volume ≤ 50 ml
(Cell Wash Solution I / NaOH-D and Cell wash Solution II / Acid Wash)		Red	Bottle empty
Sample Cleaner 1/2	ml	Yellow	Volume < yellow alarm level
(Sample Cleaner 1 and Sample Cleaner 2)		Red	Bottle empty
Bath Detergent	ml	Yellow	Volume < yellow alarm level
(EcoTergent)		Red	Bottle empty

Table E-1 **c** 501 module reagent types

ISE area



A Bar chart for the remaining number of tests

B Color-coded bar for the remaining number of tests of ISE reagents

C Color-coded bar for the calibration status

D Color-coded bar for the QC status

Figure E-19 ISE area of Reagent Overview window

The **ISE** area displays the amount of reagents using bar charts (**A**). The first bar (**B**) below each bar chart indicates the remaining number of tests for each ISE reagent. The second and the third bar below the bar charts provide additional, color-coded information on the statuses of calibration (**C**) and QC (**D**).

If this area is empty after changing an ISE reagent bottle, the analyzer has not checked the remaining volume yet.

For information about remaining volume check, see *Reagents for ISE applications* on page B-105.

Abbreviation	Unit	Description
IS	test	Internal standard solution
DIL	test	Diluent
KCL	test	Reference solution (ISE Ref.)

Table E-2 **c** 501 (ISE) reagent types

Two color-coded bars below the IS 1 and IS 2 bar charts provide additional information on the statuses of calibration and QC.

1. First colored bar (directly below volume indication field): Cal

Valid	A valid calibration is available.
Requested	A calibration has been requested.
Failed	The calibration of the bottle has failed.

2. Second colored bar: QC

Valid	QC result is within the confidence limits.
Requested	Requested for QC measurement.
Violated	QC result is not within the confidence limits.
N.A.	Not applicable.

Buttons

Detail Choose this button to display the **Detail** window. This window provides detailed information about the selected **cobas c** pack.

For information about the **Detail** window, see:
Assay cobas c pack on page E-37
Diluent cobas c pack on page E-39
Wash solution cobas c pack on page E-40

Reagent Overview window (e 601 module)

➔ **System Overview** > select a **e** 601 module >**Reagent Overview**

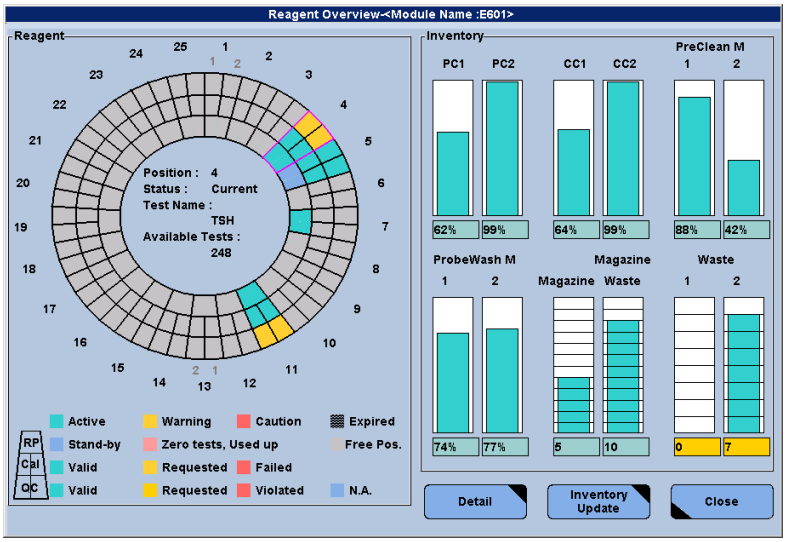


Figure E-20 Reagent Overview window (**e** 601 module)

Use this window to view the status of the reagents (**cobas e** packs, auxiliary reagents and consumables) loaded on the selected module.

This window is divided into 2 areas:

- **Reagent** area, displays the status of each **cobas e** pack
- **Inventory** area, indicates the status and the level of the auxiliary reagents and consumables

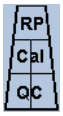
See *Auxiliary reagents* on page B-122.

Reagent area

Use this area to view the status of the **cobas e** packs, loaded on the module. This area comprises a graphic representing the reagent disk and a legend.

The 25 segments of the reagent disk graphic represent the **cobas e** pack positions within the reagent compartment. Each segment is divided into 3 subrings. The segments of the middle and outer ring are subdivided in two subsections corresponding to the two measuring channels.

Each segment shows the following information:



- **RP**: Reagent status (inner subring)
- **Cal**: Calibration status for measuring channel 1 and 2 (middle subring)
- **QC**: QC status for measuring channel 1 and 2 (outer subring)

Choosing a segment displays in the center of the graphic detailed information about the **cobas e** pack.

Legend

The legend at the bottom of the **Reagent** area explains the colors represented in the segments of the reagent disk graphic.

1. Inner ring: **RP** (Reagent Pack = **cobas e** pack)

Active	This **cobas e** pack is currently in use.
Warning	Remaining tests in this **cobas e** pack below yellow alarm level (**Utility** > **System** (**Page 2/4**) > **Reagent Level Check**).
Caution	There is no reagent, diluent, or pretreatment available for this test on this module. A reagent or pretreatment **cobas e** pack is not linked to its required partner **cobas e** pack (link status **Free**). Partner **cobas e** pack is not on board.
Stand-by	This **cobas e** pack is currently not in use. Standby **cobas e** packs are already on board but not in use at present.
Zero tests, Used up	The **cobas e** pack has been used up and is empty. Reagent, diluent, or pretreatment for this test is still available in another **cobas e** pack on this module.
Free Pos.	There is no **cobas e** pack in this position.
Expired	The **cobas e** pack has exceeded its expiration date.

2. Middle ring: **Cal** (Calibration)

Valid	A valid calibration is available.
Requested	A calibration has been requested.
Failed	The calibration of the **cobas e** pack has failed.

3. Outer ring: **QC** (Quality Control)

Valid	QC result is within the confidence limits.
Requested	A QC has been requested.
Violated	QC result is not within the confidence limits.
N.A.	Not applicable.

For diluent and pretreatment, only the inner ring (**RP**) contains information.

If the **e** 601 test is not assigned to both measuring cells, the subsection for the unassigned measuring cell is displayed in gray.

Reagent information

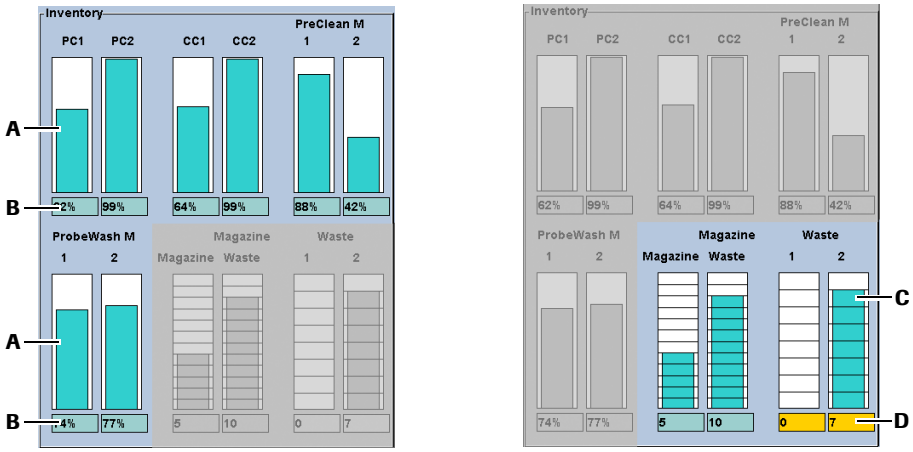
Information about the selected **cobas e** pack is displayed in the center of the reagent disk.

The following information is provided:

Position	Position of the **cobas e** pack in the reagent disk.
Status	Indicates that the **cobas e** pack is active or standby.
Test Name	Name of the **cobas e** pack.
Available Tests	Indicates the total number of determinations that can be measured with the currently available **cobas e** packs (including the standby **cobas e** packs). If a **cobas e** pack contains diluent, the total volume is displayed in ml.

Inventory area

This area displays the amount of auxiliary reagents, magazines, magazine waste and solid waste.



Auxiliary reagents

A Bar chart for the remaining amount

B Color-coded bar

Magazine waste and solid waste

C Bar chart for the remaining amount

D Color-coded bar

Figure E-21 Inventory area of Reagent Overview window

The amount of auxiliary reagents, magazines, magazine waste and solid waste is displayed as bar charts (**A**, **C**).

The bar (**B**, **D**) below the bar chart displays the remaining and provides additional, color-coded information on the statuses.

Auxiliary reagent	Unit	Color	Description
PC1/PC2	%	Yellow	One bottle empty
(ProCell bottle 1 and 2)		Red	Both bottles empty
CC1/CC2	%	Yellow	One bottle empty
(CleanCell bottle 1 and 2)		Red	Both bottles empty
PreClean M 1/2	%	Yellow	One bottle empty
(PreClean bottle 1 and 2)		Red	Both bottles empty
ProbeWash M 1/2	%	Yellow	One bottle empty
(ProbeWash bottle 1 and 2)		Red	Both bottles empty

Table E-3 **e** 601 module reagent types of Reagent Overview window

Magazine and waste	Unit	Color	Description
Magazine (Magazine with assay tips and assay cups)	Number (max 12)	Yellow	One magazine remaining
		Red	No magazines remaining
			(One blue box means one available magazine)
Magazine waste (Empty magazine)	Number (max 12)	Yellow	Space for one empty magazine remaining
		Red	No space for empty magazines remaining
			(One blue box means available space for one empty magazine)
Waste 1/2 (Solid waste for assay tips and assay cups)		Yellow	One solid waste remaining
		Red	No solid waste remaining
			(One blue box means available space for the waste of one magazine)

Table E-4 **e** 601 module reagent types of Reagent Overview window

Buttons

Detail Choose this button to display the **Detail** window. This window provides detailed information about the selected **cobas e** pack.

For information about the **Detail** window, see:
Assay cobas e pack on page E-41
Pretreatment cobas e pack on page E-43
Diluent cobas e pack on page E-45

Inventory Update Use this button to execute an inventory update for an **e** 601 module. This button is a shortcut to the **Inventory Update** maintenance window.

See *Inventory Update window* on page E-47.

Detail window

➔ **System Overview** > **Reagent Overview** > **Detail**

The **Detail** window shows different information depending on the selected **cobas c** pack or **cobas e** pack.

To get further information, choose a **Detail** window below.

Assay cobas c pack

➔ **System Overview** > select a **c** 501 module > **Reagent Overview** (select an assay **cobas c** pack) > **Detail**

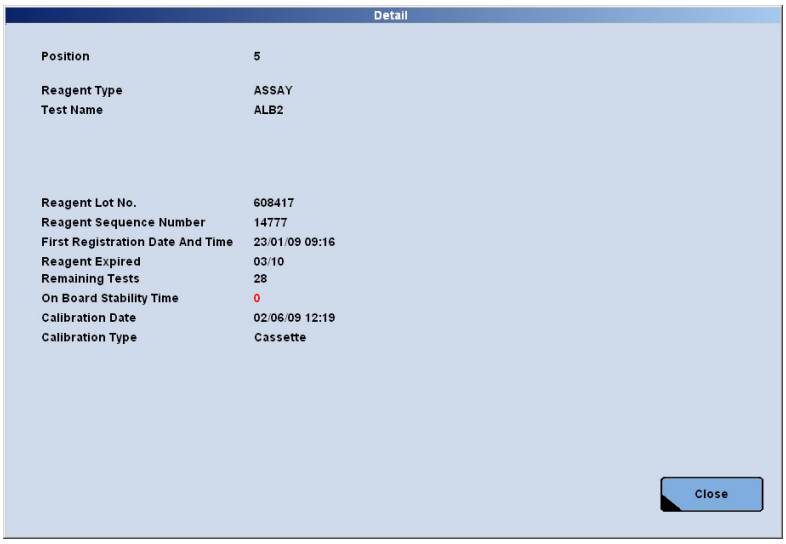


Figure E-22 Detail window of an assay

Use this window to view detailed information about the selected **cobas c** pack.

For more information about reagents, see *Reagent concept – c 501* on page B-105.

Position This field displays the position of the **cobas c** pack on the reagent rotor.

Reagent Type This field displays the type of reagent.

ASSAY	Reagent for measurement

Test Name This field displays the test name of the assay.

Reagent Lot No. This field displays the reagent lot number.

Reagent Sequence Number This field displays the sequence number of the **cobas c** pack.

The sequence number is printed as serial number on the barcode of the **cobas c** pack. The sequence number is in combination with the lot number a unique number for this **cobas c** pack.

First Registration Date and Time This field displays the first registration date and time of the **cobas c** pack.

Reagent Expired This field displays the expiration date of the **cobas c** pack.

Remaining Tests This field displays the liquid level of the **cobas c** pack.

The liquid level is displayed in number of remaining determinations.

On Board Stability time This field displays the on board stability of the **cobas c** pack in days. If the on board stability is expired, the number is displayed in red.

Calibration Date This field displays the date and time when the calibration was performed.

Calibration Type This field displays the calibration type.

Cassette	Cassette calibration
Lot	Lot calibration

For information on calibration types, see *Lot and cassette calibrations for cobas c packs* on page B-161.

Diluent cobas c pack

➔ **System Overview** > select a **c** 501 module > **Reagent Overview** (select a diluent **cobas c** pack) > **Detail**

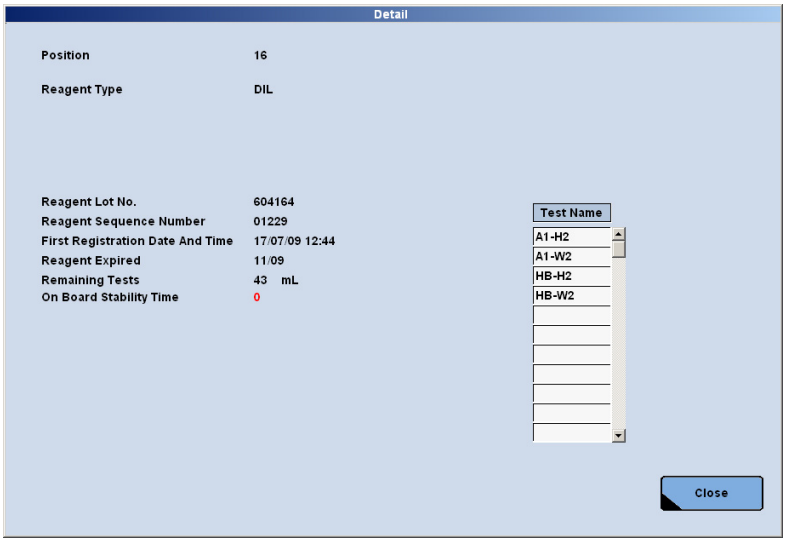


Figure E-23 Detail window of a diluent

Use this window to view detailed information about the selected diluent **cobas c** pack.

For more information about diluents, see *Diluents* on page B-110.

Position This field displays the position of the **cobas c** pack on the reagent rotor.

Reagent Type This field displays the type of reagent.

DIL	Diluent

Reagent Lot No. This field displays the reagent lot number.

Reagent Sequence Number This field displays the sequence number of the **cobas c** pack.

The sequence number is printed as serial number on the barcode of the **cobas c** pack. The sequence number is in combination with the lot number a unique number for this **cobas c** pack.

First Registration Date and Time This field displays the first registration date and time of the **cobas c** pack.

Reagent Expired This field displays the expiration date of the **cobas c** pack.

Remaining Tests This field displays the liquid level of the **cobas c** pack.

The liquid level is displayed in ml.

On Board Stability time This field displays the on board stability of the **cobas c** pack in days. If the on board stability is expired, the number is displayed in red.

Test Name This list displays the name of the applications using this diluent.

Wash solution cobas c pack

➔ **System Overview** > select a **c** 501 module > **Reagent Overview** (select a wash **cobas c** pack) > **Detail**

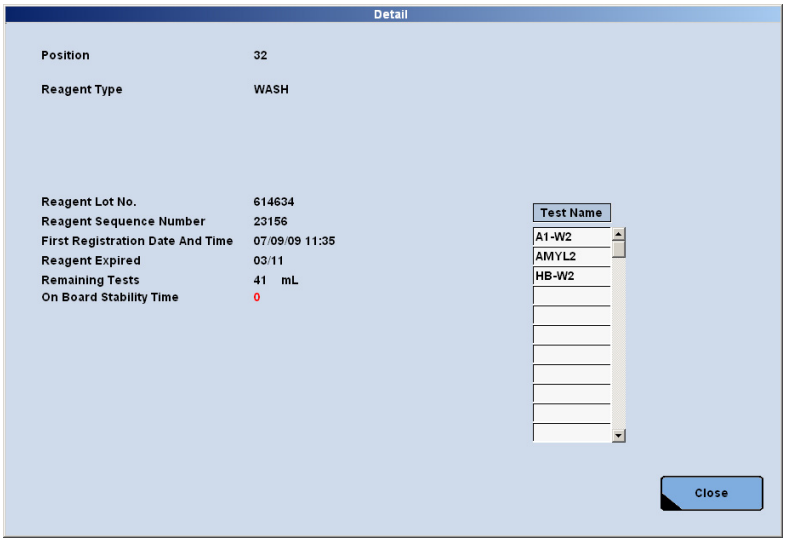


Figure E-24 Detail window of a wash solution

Use this window to view detailed information about the selected wash **cobas c** pack.

For more information about wash solutions, see *Auxiliary reagents* on page B-111.

Position This field displays the position of the **cobas c** pack on the reagent rotor.

Reagent Type This field displays the type of reagent.

WASH	Wash solution for special wash

Reagent Lot No. This field displays the reagent lot number.

Reagent Sequence Number This field displays the sequence number of the **cobas c** pack.

The sequence number is printed as serial number on the barcode of the **cobas c** pack. The sequence number is in combination with the lot number a unique number for this **cobas c** pack.

First Registration Date and Time This field displays the first registration date and time of the **cobas c** pack.

Reagent Expired This field displays the expiration date of the **cobas c** pack.

Remaining Tests This field displays the liquid level of the **cobas c** pack.

The liquid level is displayed in ml.

On Board Stability time This field displays the on board stability of the **cobas c** pack in days. If the on board stability is expired, the number is displayed in red.

Test Name This list displays the name of the applications using this wash solution.

Assay cobas e pack

➔ **System Overview** > select **e** 601 module > R**eagent Overview** (select an assay **cobas e** pack) > **Detail**

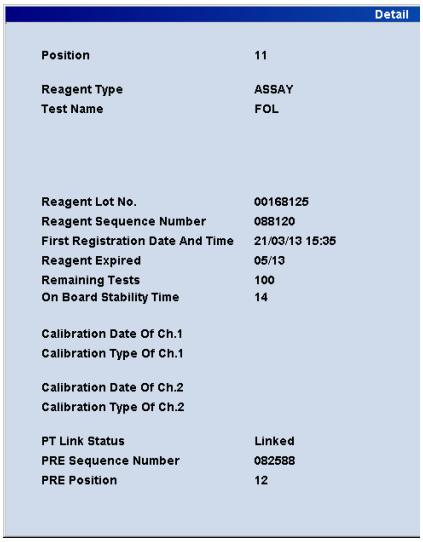


Figure E-25 Detail window of an assay

Use this window to view detailed information about the selected assay **cobas e** pack.

For more information about reagents, see *Reagent concept – e 601* on page B-114.

Position This field displays the position of the **cobas e** pack on the reagent rotor.

Reagent Type This field displays the type of reagent.

ASSAY	Reagent for measurement

Test Name This field displays the test name of the assay.

Reagent Lot No. This field displays the reagent lot number.

Reagent Sequence Number This field displays the sequence number of the **cobas e** pack.

The sequence number is printed as serial number on the barcode of the **cobas e** pack. The sequence number is in combination with the lot number a unique number for this **cobas e** pack.

First Registration Date and Time This field displays the first registration date and time of the **cobas e** pack.

Reagent Expired This field displays the expiration date of the **cobas e** pack.

Remaining Tests This field displays the reagent level of the **cobas e** pack.

The reagent level is displayed in number of remaining determinations. If the **cobas e** pack is empty a red zero is displayed.

For linked **cobas e** packs, this field displays the number of remaining determinations that are available for this linked pair. If the number of remaining test is red the **cobas e** pack was masked.

On Board Stability time This field displays the on board stability of the **cobas e** pack in days. If the on board stability is expired, the number is displayed in red.

Calibration Date Of Ch.1/Ch.2 This field displays the date and time when the calibration of the corresponding measuring channel was performed.

Calibration Type Of Ch.1/Ch.2 This field displays the calibration type of the corresponding measuring channel.

Reagent Pack	Cassette calibration
Lot	Lot calibration

For information on calibration types, see *Lot and cassette calibrations for cobas e packs* on page B-163.

PT Link Status The **PT Link Status** field displays the link status.

The **PT Link Status** field is only available for **cobas e** packs which can be linked to a partner **cobas e** pack.

Free	The assay **cobas e** pack is not yet linked to any pretreatment **cobas e** pack and has not been used before. Free **cobas e** packs are not available for measurement.
Linked	The assay **cobas e** pack is linked to a suitable pretreatment **cobas e** pack. If both **cobas e** packs are on board, this **cobas e** pack is available for use.

PRE Sequence Number The **PRE Sequence Number** field displays the sequence number of the linked pretreatment **cobas e** pack. If ----- is displayed, there is no linked **cobas e** pack (link status: **Free**).

The **PRE Sequence Number** field is only available for **cobas e** packs which can be linked to a partner **cobas e** pack.

PRE Position The **PRE Position** field displays the position of the linked pretreatment **cobas e** pack on the reagent rotor.

A position is displayed only if the **cobas e** pack is linked (link status: **Linked**) and if the linked pretreatment **cobas e** pack is on board. Otherwise **Nothing** is displayed.

The **PRE Position** field is only available for **cobas e** packs which can be linked to a partner **cobas e** pack.

Pretreatment cobas e pack

➔ **System Overview** > select **e** 601 module > R**eagent Overview** (select an pretreatment **cobas e** pack) > **Detail**

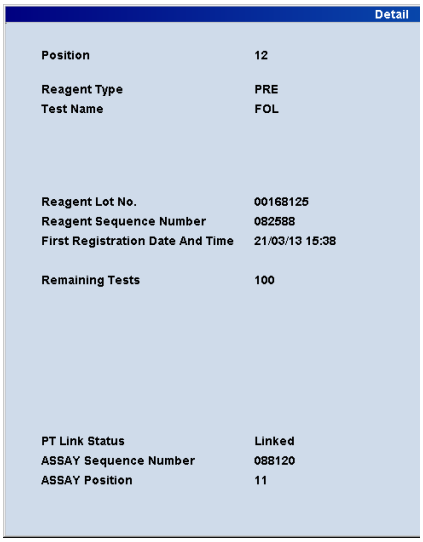


Figure E-26 Detail window of a pretreatment

Use this window to view detailed information about the selected pretreatment **cobas e** pack.

For more information about pretreatments, see *Pretreatments and the PT link function* on page B-118.

Position This field displays the position of the **cobas e** pack on the reagent rotor.

Reagent Type This field displays the type of reagent.

PRE	Pretreatment for measurement

Test Name This field displays the test name of the pretreatment.

Reagent Lot No. This field displays the reagent lot number.

Reagent Sequence Number This field displays the sequence number of the **cobas e** pack.

The sequence number is printed as serial number on the barcode of the **cobas e** pack. The sequence number is in combination with the lot number a unique number for this **cobas e** pack.

First Registration Date and Time This field displays the first registration date and time of the **cobas e** pack.

Reagent Expired This field displays the expiration date of the **cobas e** pack in the corresponding position.

Remaining Tests This field displays the reagent level of the **cobas e** pack.

The reagent level is displayed in number of remaining determinations. If the **cobas e** pack is empty a red zero is displayed.

For linked **cobas e** packs, this field displays the number of remaining determinations that are available for this linked pair. If the number of remaining test is red the **cobas e** pack was masked.

PT Link Status This field displays the link status.

Free	The **cobas e** pack is not yet linked to any assay **cobas e** pack and has not been used before. Free **cobas e** packs are not available for measurement.
Linked	The **cobas e** pack is linked to a suitable assay **cobas e** pack. If both **cobas e** packs are on board, this **cobas e** pack is available for use.

ASSAY Sequence Number This field displays the sequence number of the linked assay **cobas e** pack.

If ----- is displayed, there is no linked **cobas e** pack (link status: **Free**).

ASSAY Position This field displays the position of the linked assay **cobas e** pack on the reagent rotor.

A position is displayed only if the **cobas e** pack is linked (link status: **Linked**) and if the linked **cobas e** pack is on board. Otherwise **Nothing** is displayed.

Diluent cobas e pack

➔ **System Overview** > select a **e** 601 module > **Reagent Overview** (select a diluent **cobas e** pack) > **Detail**

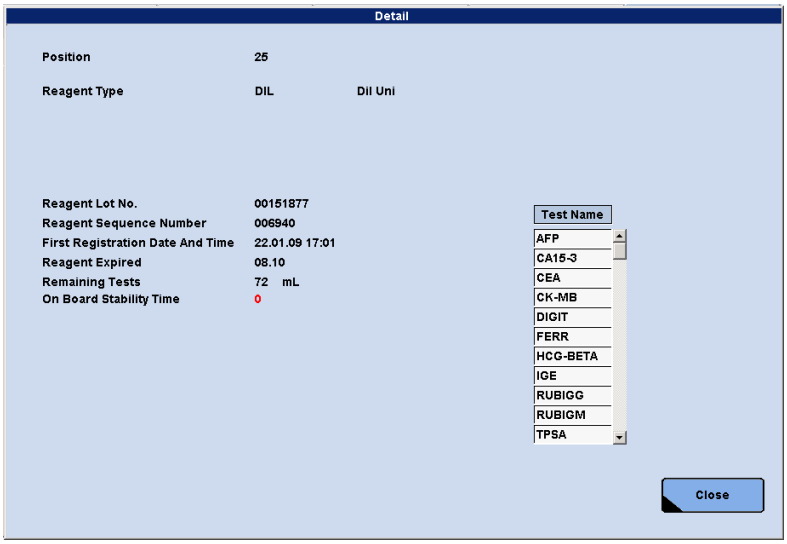


Figure E-27 Detail window of a diluent

Use this window to view detailed information about the selected diluent **cobas e** pack.

For more information about diluents, see *Diluents* on page B-120.

Position This field displays the position of the **cobas e** pack on the reagent rotor.

Reagent Type This field displays the type of reagent.

DIL	Diluent

The diluent name is displayed to the right of the reagent type.

Reagent Lot No. This field displays the reagent lot number.

Reagent Sequence Number This field displays the sequence number of the **cobas e** pack.

The sequence number is printed as serial number on the barcode of the **cobas e** pack. The sequence number is in combination with the lot number a unique number for this **cobas e** pack.

First Registration Date and Time This field displays the first registration date and time of the **cobas e** pack.

Reagent Expired This field displays the expiration date of the **cobas e** pack.

Remaining Tests This field displays the liquid level of the **cobas e** pack.

The liquid level is displayed in ml.

On Board Stability Time This field displays the on board stability of the **cobas e** pack in days. If the on board stability is expired, the number is displayed in red.

Test Name This list displays the name of the applications using this diluent.

Inventory Update window

➔ **System Overview** > select a **e** 601 module > **Reagent Overview** > **Inventory Update**

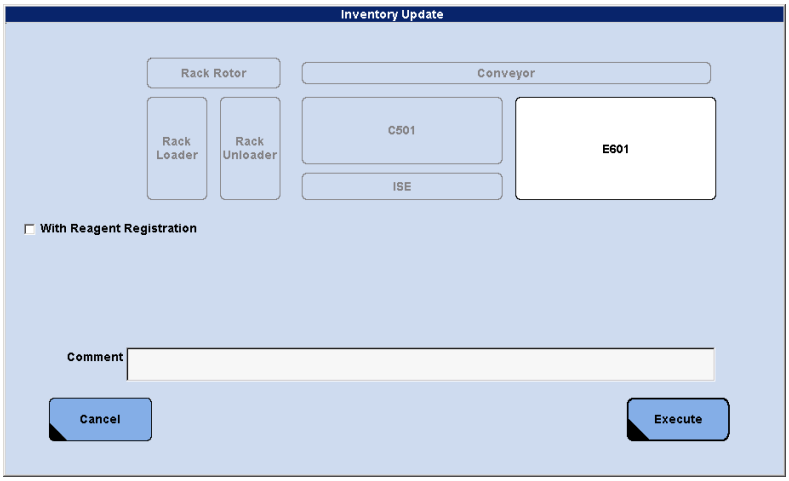


Figure E-28 Inventory Update window

If inventory update is executed the following actions are performed:

- Update the number of magazines in the magazine lifter
- Check and update of ProbeWash bottle 1 and 2

The inventory update function is only available for **e** 601 module.

With Reagent Registration Select this check box to initiate a reagent registration as part of the inventory update.

Temperature window (e 601 module)

➔ **System Overview** > select a **e** 601 module > **Temperature**

Choose this button to display the **Temperature** window.

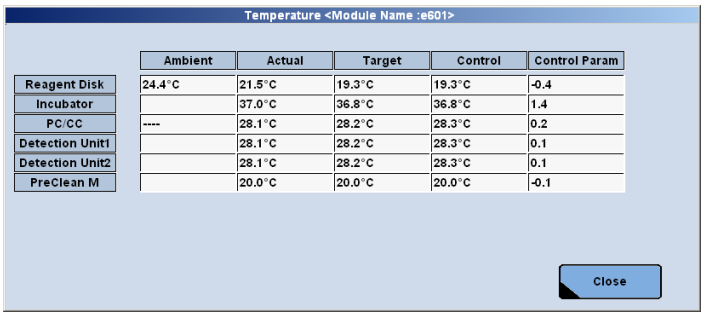


Figure E-29 Temperature window (**e** 601 module)

This window displays the ambient and actual temperatures for the module currently selected.

Global screens

This chapter provides a detailed description of the global screens which include the **Stop**, **Shutdown**, **Sampling Stop**, **Alarm**, **Print** and **Start Conditions** screens. The functions of the global screens relate to the whole system. You can access the global screens via the global buttons on the right-hand side of the screen at anytime regardless of which part of the software is currently displayed.

In this chapter *Chapter* 22

Overview E-55
Global buttons E-56
Stop screen E-58
Shut Down screen E-59
Sleep window E-61
Waking up the analyzer from Sleep mode E-62
Logon screen E-63
S. Stop screen E-64
Alarm screen E-65
Buttons E-66
Sound Setting window E-67
Print screen E-68
Tabs E-68
Buttons E-69
Print View window E-70
Jump window E-72
Print window E-73
Media Write window E-74
Media area E-74
Reports E-75
Workplace print screen E-77
Data Monitor/Report E-77
Print Format area E-77
Data Type area E-78
Print Data area E-78
Buttons E-78
Data Monitor report (monitor format) E-79
Data Monitor report (monitor format) explanation E-79

Data Monitor report (report format) E-81
Data Monitor report (report format) explanation E-81
Reaction Monitor E-84
Data Type area E-84
Wavelength area E-84
Buttons E-85
Reaction Monitor report E-85
Reaction Monitor report explanation E-86
Requisition List E-88
Requisition List print screen (barcode mode) E-88
Requisition List print screen (non-barcode mode) E-89
Buttons E-89
Requisition List report E-90
Requisition List report explanation E-90
Rerun List E-92
Buttons E-92
Rerun List report E-93
Rerun List report explanation E-93
Precision Check E-95
Buttons E-95
Precision Check report E-96
Precision Check report explanation E-96
Profile List E-97
Buttons E-97
Profile List report E-98
Profile List report explanation E-98
Reagent Information print screen E-99
Reagent Status E-99
Buttons E-100
Reagent Status report E-101
Reagent Status report explanation E-102
Reagent Load/Unload List E-104
Buttons E-104
Reagent Load/Unload List report E-105
Reagent Load/Unload List report explanation E-105
Calibration print screen E-107
Reaction Monitor E-107
Standard area E-107
Abs. Data area E-107
Wavelength area E-108
Buttons E-108
Calibrator Load List E-109
Buttons E-109
Calibration Load List report E-110
Calibration Load List report explanation E-110
Calibration Trace E-111
Date Range area E-111
Buttons E-111
Calibration Trace report (c 501 (ISE)) E-112
Calibration Trace report (c 501 (ISE)) explanation E-113

Calibration Trace report (c 501 module) E-114
Calibration Trace report (c 501 module) explanation E-115
Calibration Trace report (e 601 module) E-115
Calibration Trace report (e 601 module) explanation E-116
Calibration Result E-117
Buttons E-117
Calibration Result report E-118
Calibration Result report explanation E-118
Calibration Request List E-119
Buttons E-119
Calibration Request List report E-120
Calibration Request List report explanation E-120
Calibration Monitor report E-121
ISE Calibration Monitor report E-121
ISE Calibration Monitor report explanation E-122
Photometric Calibration Monitor report E-123
Photometric Calibration Monitor report explanation E-123
Immunology Calibration Monitor report E-125
Immunology Calibration Monitor report explanation E-126
Header E-126
General information about the calibrator E-126
Results and calibration quality criteria E-127
QC print screen E-129
Individual QC Chart E-129
Data Type area E-129
Date Range area E-130
Buttons E-130
Individual QC Chart report E-131
Individual QC Chart report explanation E-132
Header E-132
Chart E-132
Results E-133
Statistics E-134
Individual QC List E-135
Buttons E-135
Individual QC List report E-136
Individual QC List report explanation E-136
Cumulative QC Chart E-138
Date Range area E-138
Buttons E-138
Cumulative QC Chart report E-139
Cumulative QC Chart report explanation E-139
Header E-140
Chart E-140
Results E-140
Statistics E-141
Cumulative QC List E-142
Buttons E-142
Cumulative QC List report E-143
Cumulative QC List report explanation E-143

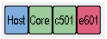
QC Load List E-144
Buttons E-144
QC Load List report E-145
QC Load List report explanation E-145
QC Request List E-147
Buttons E-147
QC Request List report E-148
QC Request List report explanation E-148
Utility print screen E-149
Alarm Trace E-149
Alarm Trace area E-149
Alarm Information area E-150
Date Range area E-150
Buttons E-150
Daily Alarm Trace report E-151
Daily Alarm Trace report explanation E-151
Cumulative Alarm Trace report E-152
Cumulative Alarm Trace report explanation E-153
Communication Trace E-154
Communication Information area E-154
Buttons E-154
System Communication Trace report E-155
Communication Trace report explanation E-155
Operator ID Trace E-156
Date Range area E-156
Buttons E-157
Operator ID Trace report E-157
Operator ID Trace report explanation E-157
Cumulative Operation List E-158
Buttons E-158
Cumulative Operations List report E-159
Cumulative Operations List report explanation E-160
Application Parameters E-161
Buttons E-161
Application Parameters report E-162
Application Parameters report explanation E-162
Report Example E-163
Buttons E-163
Report Example E-164
Cell Blank E-165
Buttons E-165
Cell Blank Measurements report E-166
Cell Blank Measurements report explanation E-166
Maintenance Report E-167
Maintenance area E-167
Module area E-167
Date Range area E-168
Buttons E-168
Maintenance Report E-169
Maintenance report explanation E-170

Cuvette History E-171
Buttons E-171
Cuvette History report E-172
Cuvette History report explanation E-172
Rack Archival Report E-175
Rack Archival area E-175
Date Range area E-175
Buttons E-176
Rack Archival Report E-176
Rack Archival Report explanation E-176
Pressure Sensor Voltage Adjust E-178
Buttons E-178
Reports Printed from Utility > Maintenance E-179
Hard Disk Check report E-179
Hard Disk Check report explanation E-181
Backup Disk report E-182
Backup Disk report explanation E-182
ISE Check report E-183
ISE Check report explanation E-183
Barcode Reader Check report E-184
Sample Barcode Reader Check report E-184
Sample Barcode Reader Check report explanation E-184
Reagent Barcode Reader Check report E-185
Reagent Barcode Reader Check report explanation E-185
Start Conditions screen E-186
Start Sample No. area (non-barcode mode) E-187
Start Up Pipe Setting area E-187
Automatic Rerun area E-188
Host Setting area E-188
Rack Reception Mode area E-189
MPA Connection Mode area E-189
Buttons E-189
Pipe Function window E-190
Automatic Rerun window E-191
Host Setting window E-192
Rack Reception Mode window E-193
MPA Connection Mode window E-194
Masking window E-195
Module Masking window E-197
Default Profile Per Sample Type window E-198
Buttons E-199
Confirmation window E-199
No Help available E-199

Overview

You can access the global screens using the global buttons on the right side of the screen, regardless of the current software screen displayed:

- **USB**
- **Stop**
- **Shut Down**
- **S. Stop**
- **Alarm**
- **Print**
- **Start**



It is possible to display the **System Overview** screen—regardless of the current software screen display—by choosing the icon in the top left corner of the screen or by pressing F12.

For information about the **System Overview** screen, see *System Overview screen* on page E-5.

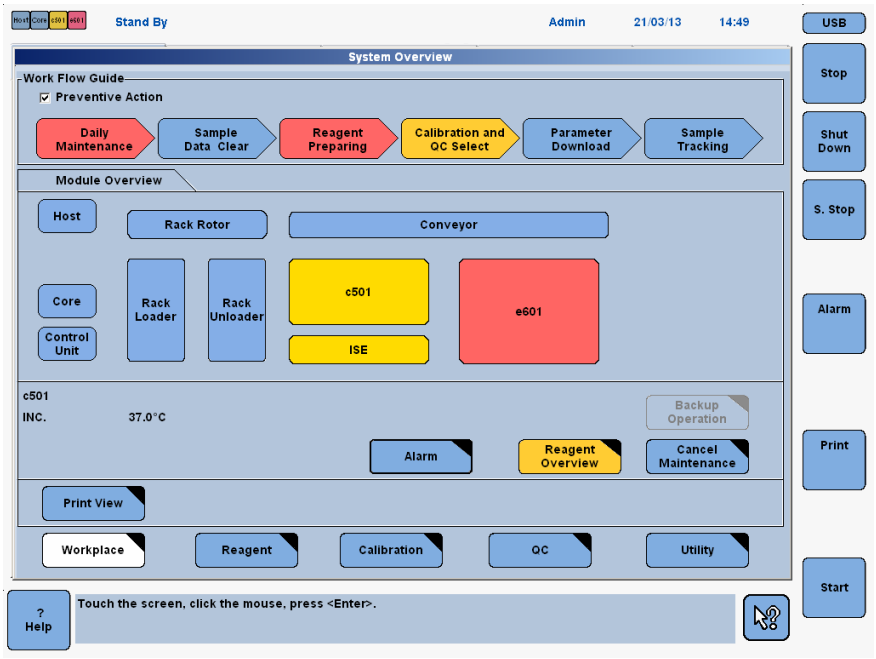


Figure E-30 System Overview screen with global buttons

Global buttons

The buttons on the right of the user interface are referred to as global buttons because they can be accessed regardless of which part of the software is currently displayed.

USB Use this button to remove a USB storage device. After confirmation you can remove the USB storage device.

For more information, see *Using a USB storage device* on page B-247.

Stop (global button) Use this button to interrupt operation of the instrument and force all modules to stop processing at the end of the current mechanical cycle.

For more information, see *Stop screen* on page E-58.

Shut down (global button) Use this button to change operator (log off), to put the analyzer into sleep mode or to shut down the analyzer.

For more information, see *Shut Down screen* on page E-59.

S. Stop (global button) Use this button to perform a sample stop. After confirmation the loader stops processing new samples; all other functions related to test processing continue until results are available.

For more information, see *S. Stop screen* on page E-64.

Alarm (global button) Use this button to view alarm information. If an alarm was issued, this global button flashes. In this case it is necessary to open the **Alarm** screen to view the alarm.

For more information, see *Alarm screen* on page E-65.

Print (global button) Use this button to open the **Print** screen and select reports or lists to be printed or viewed. The software is context-sensitive and automatically displays the **Print** screen corresponding to the software area currently displayed.

For more information, see *Print screen* on page E-68.

Start (global button) Use this button to open the **Start Conditions** screen and start the analyzer or to select operating parameters.

For more information, see *Start Conditions screen* on page E-186.

System Overview icon

The **System Overview** icon, in the top left of the status line represents the system configuration (i.e. the modules of the system). The color of these modules reflects the status of the module. Choosing a module in the **System Overview** icon displays the **System Overview** screen with that module selected in the **Module Overview** area.

For more information, see *System Overview screen* on page E-5.



Direct Help: Use this button to directly display brief information for a single software element, such as a button or field. Use this help feature if you only require a tooltip about an element.

First choose this button and wait until a question mark (**?**) is displayed next to the pointer. Then choose the screen element for which you want detailed information. A tooltip (pop-up window) is displayed containing information about this screen element.



The Direct Help can only provide short tooltips

If you require more information about an element, please press <F1> to open the F1 Help system.

For more detailed information, see *About Direct Help* on page B-20.

? Help

F1 Help: Use this button to open the **Help** window. The context sensitive entry displays text relating to your current location in the software.



Operator's Manual included in the F1 Help system

The Operator's Manual is included in the F1 Help system. This allows you to search for information throughout the software reference and the manual. All cross-references are implemented as hyperlinks.

For more information, see *The help system of the instrument* on page B-13.

Stop screen

➔ **Stop** (global button) or press the <F4> key

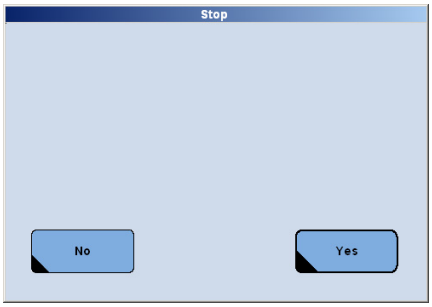


Figure E-31 Stop screen

Use this screen to force all **cobas** 6000 analyzer series modules to stop processing at the end of the current mechanical cycle. The **Stop** screen asks for confirmation before sending the “Stop” command. Choose **Yes** to confirm or choose **No** to retract the command.

Shut Down screen

➔ **Shut Down** (global button)

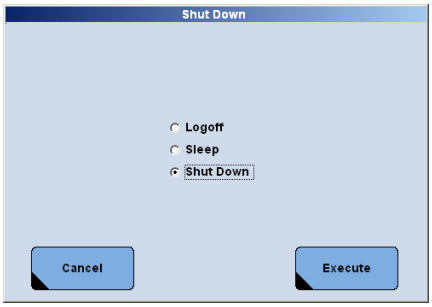


Figure E-32 Shut Down screen

Use this button to change operator (**log off**), to put the analyzer into sleep mode or to shut down the analyzer. Choose **Execute** to execute the selected option. Choose **Cancel** to close the screen without any changes.

Logoff The analyzer remains powered on and in operation after you have logged off. It is possible to print a trace of the operators who have used the analyzer.

For more information, see:
Logon screen on page E-63
Operator ID Trace report on page E-157

Sleep During sleep mode most of the parts are powered off. Only the control unit, cooling compartment and circuit board are powered on.

Sleep mode provides the possibility of an automatic start-up on the next day. Thus, the system can perform initialization and any programmed maintenance pipe in the absence of an operator, before the beginning of a working session. When the operator arrives, the analyzer is ready for operation. The analyzer is initialized ten minutes before the specified time. Thereafter the selected maintenance pipe is performed.

The sleep function can also be included in a maintenance pipe, so that the system goes automatically into Sleep status after performing the pipe.

The sleep mode can be manually interrupted at any time by the operator.

See *Waking up the analyzer from Sleep mode* on page E-62.

The wake up time and the maintenance pipe can be set under **Utility** > **System** > **Power Up Pipe**.

For more information, see:
Power Up Pipe Setting window on page E-400
To enter sleep mode on page B-75
Using maintenance pipe functions on page C-15
Sleep Pipe function with green wash rack on page C-17

Shut Down In Shutdown status the control unit is powered off. After the control unit is powered off, the analyzer must be manually switched off.

For more information, see *To shut down the analyzer* on page B-75.

After shutting down the analyzer, check individual parts of the instrument according to the given maintenance recommendations.

For more information, see *Checks after shutdown* on page B-76.

Sleep window

➔ **Shut Down** (global button) > **Sleep**

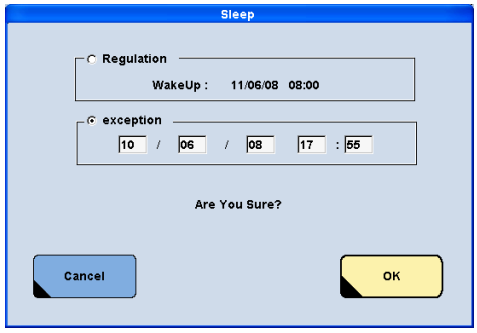


Figure E-33 Sleep window

Use this screen to check the wake up time of the analyzer. Choose **OK** to put the analyzer into sleep mode and to exit the analyzer software. **Cancel** closes the screen without putting the analyzer into sleep mode.

For more information about sleep mode, see *Shut Down screen* on page E-59.

Regulation This entry displays the wake up time set under **Utility** > **System** > **Power Up Pipe**.

For more information, see *Power Up Pipe Setting window* on page E-400.

Exception Enter a date and time, if the analyzer software should wake up at a different time.

Waking up the analyzer from Sleep mode

➔ **Shut Down** (global button) > **Sleep** > **OK**

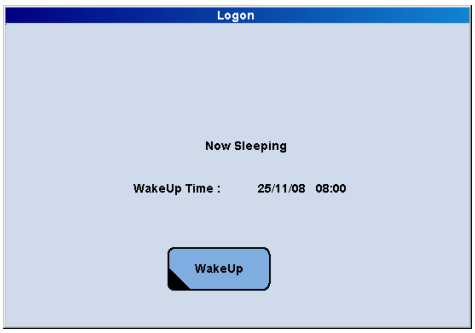


Figure E-34 Logon (from sleeping) window

After the analyzer was put into sleep mode, the **Logon** (from sleeping) window is displayed. The sleep mode can be manually interrupted at any time by the operator.

Choose **WakeUp** to interrupt the sleep mode manually.

A confirmation window is displayed. If you want to perform a wake up pipe, you can select the respective option.

Choose **OK** to start the wake up process.

The analyzer performs initialization and the **Logon** screen is displayed.

For more information about sleep mode, see *Sleep window* on page E-61.

Logon screen

If the system is in password protection mode, the **Logon** screen is displayed whenever the system is powered on or whenever a Logoff has been performed on the **Shut Down** screen.



Figure E-35 Logon screen

It is possible to print a trace of the operators who have used the system.

See *Operator ID Trace report* on page E-157.

Operator ID Type the operator ID in the **Operator ID** text box (up to 6 characters). The operator ID is defined in **Utility** > **System** (**Page 3/4**) > **Operator ID**.

See *Operator ID Setting window* on page E-402.

Password Type the password in the **Password** text box (up to 8 characters, upper or lower case). The password is defined at the first log-in of the operator ID.

Passwords are case sensitive.

OK Choose **OK** to log onto the system.

S. Stop screen

➔ **S. Stop** (global button) or press the <F3> key

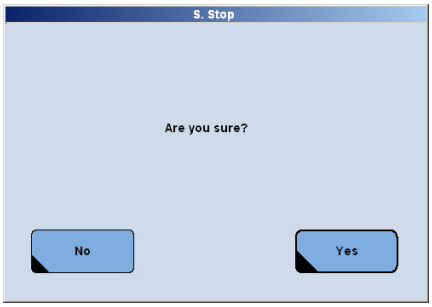


Figure E-36 Sample Stop screen

Use this screen to perform a sample stop. The **S. Stop** screen asks for confirmation before sending the S. Stop command. Choose **Yes** to confirm or choose **No** to retract the command.

During a sample stop, the loader stops processing new samples; all other functions related to test processing continue until results are available.

A sample stop can only be performed when the system is in operation. When activated a yellow bar is displayed in the global button.

Alarm screen

➔ **Alarm** (global button) or press the <F11> key

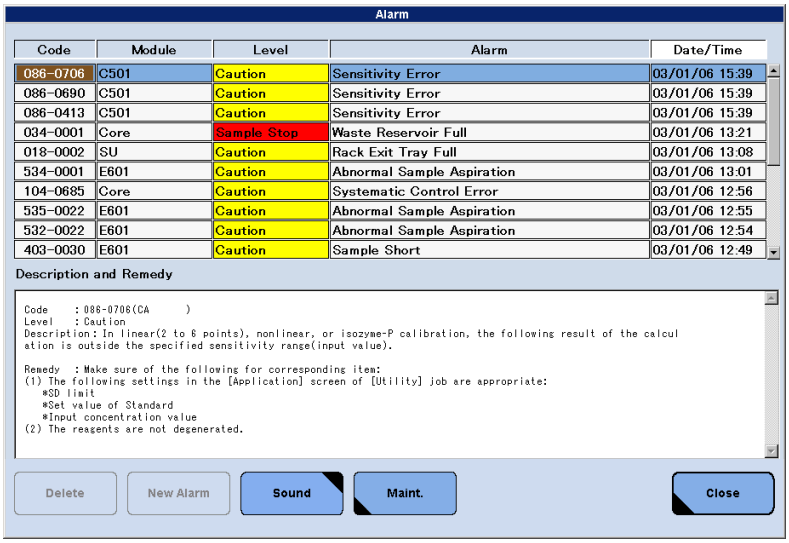


Figure E-37 Alarm screen

Use this screen to view instrument alarm information and to change the sound of the audible alarms. The **Maintenance** screen can also be accessed from this screen if maintenance is required as indicated by an alarm.

See *Check system alarms* on page B-34.

Alarms are stored on the system database and can be printed via the **Alarm Trace** report from the **Utility print** screen.

See *Alarm Trace* on page E-149.

- If an instrument alarm is displayed in the **Alarm** list follow the remedy in the **Description and Remedy** list to troubleshoot the alarm. Only after completing the remedy described should the alarm be deleted.
- Alarm codes are not duplicated. If an alarm is issued with the same alarm code and subcode more than once, the alarm is not updated with the new information. Therefore, delete each alarm after resolving the situation.
- Note the alarm code in case you have to contact Roche service representative. You can print deleted instrument alarms from the **Alarm** screen via **Print** > **Utility** > **Alarm Trace**.
- It may also be helpful to print a screenshot of the **Alarm** screen. To print a screenshot, press <Shift> and <Print Screen> at the same time.

The upper part of the screen displays a list of the alarms. The alarm list can be sorted by any of its 5 columns: **Code**, **Module**, **Level**, **Alarm** (Name), and **Date/Time**. A white background distinguishes the selected column tab.

Code The **Code** column displays the alarm code and subcode.

See *Alarm Trace* on page E-149.

Module The **Module** column displays the module for which the alarm code was issued.

Level The **Level** column displays the level of each alarm.

Alarm The **Alarm** column displays the name of the alarm.

Date/Time The **Date/Time** column displays the date and time the alarm occurred.

Description and Remedy This area list displays the alarm **Code**, **Level**, **Description** and **Remedy** for the selected alarm. Follow the steps in the **Remedy** section to troubleshoot the alarm.

See *Alarm Trace* on page E-149.

Buttons

Delete Use this button to delete the alarm selected in the **Alarm** list. Single alarms, a range of alarms or nonconsecutive alarms can be selected.

New Alarm Use this button to display any new alarms that occur while viewing the **Alarm** screen. If a new alarm occurs, this button turns yellow or red, depending on the alarm level. After choosing the **New Alarm** button, the screen is refreshed and the new alarm(s) is displayed.

Sound Use this button to set alarm patterns and tones for the different alarm levels. Use this button to also enable and disable audible alarms. Choosing this button displays the **Sound Setting** window.

See *Sound Setting window* on page E-67.

Maint. If in the Description and Remedy area maintenance is required, use this button to display the **Utility** > **Maintenance** screen to initiate the required maintenance.

See *Maintenance screen* on page E-420.

Sound Setting window

➔ **Alarm** (global button) > **Sound**



Figure E-38 Sound Setting window

Use this window to turn audible alarms on or off on the core and control units (the core unit alarms must also be enabled on the **Alarm Setting** window). The sound of the audible alarms on the control unit can also be changed.

See *Alarm Setting window* on page E-374.

Sound Select this check box to activate the control unit audible alarm.

Core unit alarms can be toggled on and off on **Utility** > **System** > **Alarm**.

When the **Sound** check box is selected, the **Tone** and **Interval** list boxes are enabled.

Level This information field displays the different alarm levels to which audible alarms can be assigned. The levels are **E. Stop**, **Stop**, **S.Stop** and **Warning**.

Tone Use these list boxes to select the desired tones for the audible alarms on the control unit. There are 10 tones to choose from (1-10). The lower the number; the lower the tone.

Interval Use these list boxes to select the desired patterns for the audible alarms on the control unit. There are 10 intervals to choose from (1-10). The lower the number; the longer the interval.

Test Use this column to test the sounds selected in the **Tone** and **Interval** list boxes. Choose the **Play** button to listen to the selected tone and pattern. This button changes to **Stop** when the alarm is sounding. Choose the **Stop** button to end the test.

Print screen

➔ **Print** (global button) or press the <Print> key

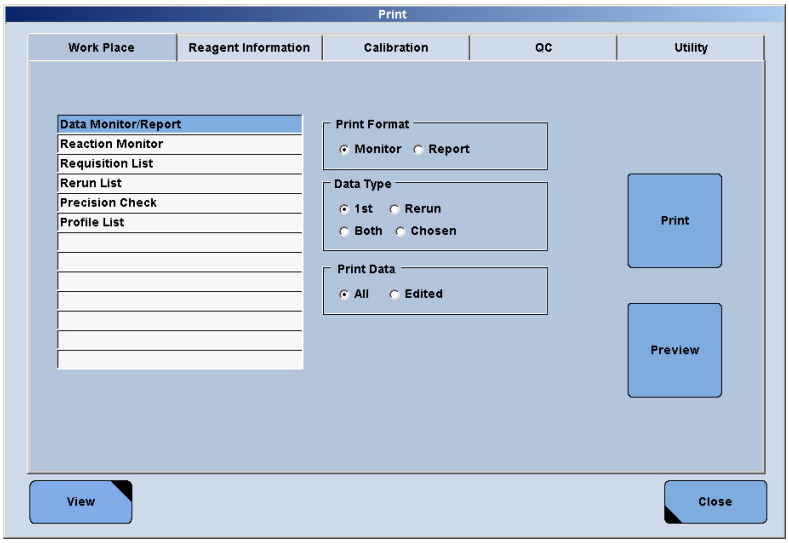


Figure E-39 Print screen (example)

Use the **Print** screen to select the report to be printed or viewed. The software is context-sensitive, and automatically displays the **Print** screen corresponding to the software area currently displayed.

The **Print** screen displays the tabs: **Work Place**, **Reagent Information**, **Calibration**, **QC** and **Utility**. Selecting one of these tabs displays the available corresponding reports.

Report Selection list

Select the report to be printed or viewed from the list. Some reports may require that specific parameters are defined prior to viewing or printing.

👁 For more information, see:
Reports on page E-75
Workplace print screen on page E-77
Reagent Load/Unload List on page E-104
Calibration print screen on page E-107
QC print screen on page E-129
Utility print screen on page E-149

Tabs

Work Place

The **Print > Work Place** screen displays a list of reports relating to the **Workplace** menu. The screen changes depending on the report selected and whether the system is in barcode mode or non-barcode mode.

The screen changes depending on the report selected and whether the system is in barcode mode or non-barcode mode.

👁 See *Workplace print screen* on page E-77.

Reagent Information Choose this tab to display the list of available reports corresponding to the **Reagent** menu. Report options include: **Reagent Status** and **Reagent Load/Unload List**.

The screen changes depending on the report selected.

See *Reagent Load/Unload List* on page E-104.

Calibration Choose this tab to display the list of available reports corresponding to the **Calibration** menu. Report options include: **Reaction Monitor**, **Calibrator Load List**, **Calibration Trace**, **Calibration Result** and **Calibration Request List**.

The screen changes depending on the report selected.

See *Calibration print screen* on page E-107.

QC Choose this tab to display the list of available reports corresponding to the Quality Control (**QC**) menu. Report options include: I**ndividual QC Chart**, I**ndividual QC List**, **Cumulative QC Chart**, **Cumulative QC List**, **QC Load List** and **QC Request**. The screen changes depending on the report selected.

See *QC print screen* on page E-129.

Utility Choose this tab to display the list of available reports corresponding to the **Utility** menu. Report options include: **Alarm Trace**, **Communication Trace**, **Operator ID Trace**, **Cumulative Operations List**, **Application Parameters**, R**eport Example**, **Cell Blank**, **Maintenance Report**, **Cuvette History**, **Rack Archival Report**, and **Pressure Sensor Voltage Adjust**.

The screen changes depending on the report selected.

See *Utility print screen* on page E-149.

Buttons

Print/OK Choose this button to send the selected list or report to the printer and to store it in the print buffer.

Preview Choose **Preview** and then **View** to display a preview of the currently selected report without printing the report.

View Choose this button to view the lists and reports currently in the print buffer and also to write them to disk.

For more information, see:
Print View window on page E-70
Media Write window on page E-74



When printed, the reports can produce numerous pages, occupying much of the print buffer.

<Scroll Lock> Use this key to display the **Cancel Print** window to cancel the printout

Print View window

➔ **Print** (global button) > **View**

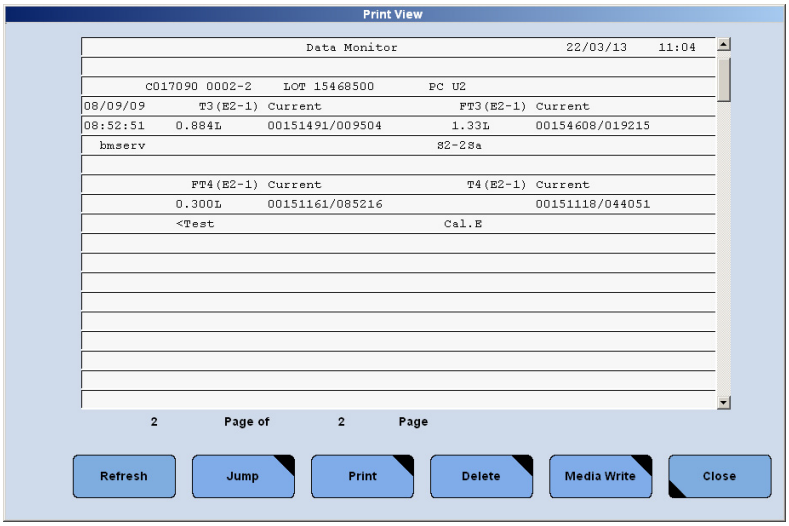


Figure E-40 Print View window

Use this window to display the reports currently in the print buffer. Up to 800 pages can be stored in the print buffer. After that point, the first page is deleted for every page that is added.

Example: If the software shows you have 1680 pages, you can only view the pages 880 to 1680. The pages 1 to 879 are deleted.

Scroll to the appropriate page to display the desired report.

The information is deleted from the **Print View** window when the system is powered OFF or when you use the delete function described below.

Refresh When the print buffer is updated this button turns yellow. Choosing the **Refresh** button when it is yellow updates the **Print View** window with the new information in the print buffer.

Jump Use this button to move between all viewable pages of the reports in the print buffer.

See *Jump window* on page E-72.

Print Use this button to print pages from the print buffer. Choosing this button displays the **Print** window. Use this window to define the pages to be printed from the print buffer.

See *Print window* on page E-73.

Delete Use this button to delete the entire contents of the print buffer. Choosing this button displays the **Delete Confirmation** window. Choose **Yes** to confirm or choose **No** to retract the command.

Media Write Use this button to write the currently selected report to a storage medium. Choosing this button displays the **Media Write** window. Use this window to enter a file name, to select the storage medium and the pages to be stored.

See *Media Write window* on page E-74.

Jump window

➔ **Print** (global button) > **View** > **Jump**

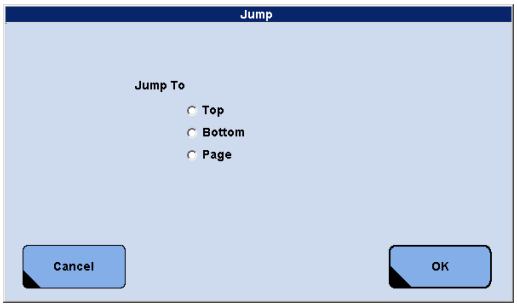


Figure E-41 Jump window

Use this window to move between all viewable pages of the reports in the print buffer.

Top Select the **Top** option to move to the top of the viewable reports.

Bottom Select the **Bottom** option to move to the bottom of the viewable reports.

Page Select the **Page** option to enable the **Page Number** text box. Enter the page number you wish to jump to.

Print window

➔ **Print** (global button) > **View** > **Print**

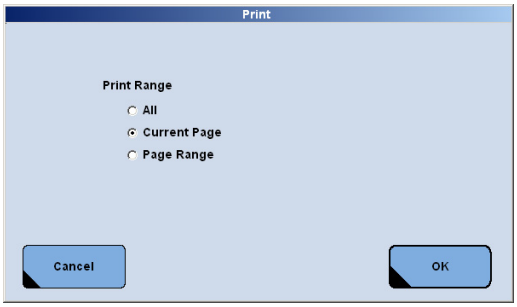


Figure E-42 Print window

Use this window to define the page(s) to print.

Use this option to define the page(s) to print.

All Select the **All** option to print all pages.

Current Page Select the **Current Page** option to print the page currently selected on the **Print View** window.

The number of the currently selected page is shown in the bottom of the **Print View** window.

Page Range Select the **Page Range** option to print a range of pages. Type the first page number of the range in the first text box and press <Enter>. Type the last page number of the range in the second text box and press <Enter>.

Media Write window

➔ **Print** (global button) > **View** > **Media Write**

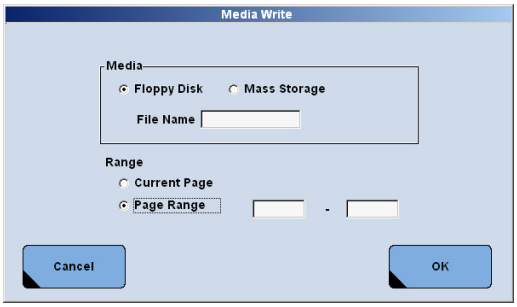


Figure E-43 Media Write window

Use this window to copy the print view information to a selected storage medium and to enter a file name.

The file created can be read as a text file by standard PCs.

Range area Use this area to define the pages to be written to the selected storage medium.

Current Page Select **Current Page** to write the page currently selected on the **Print View** window to the selected storage medium.

See *Print View window* on page E-70.

Page Range Select **Page Range** to write a range of pages to the selected storage medium. Type the first page number of the range in the first text box and press <Enter>. Type the last page number of the range in the second text box and press <Enter>.

Media area

Use this area to set, which storage medium is used for writing the copy of the print view information.

Option	Description
Floppy Disk	Select this option to write the copy of the print view information to a floppy disk.
Mass Storage	Select this option to write the copy of the print view information to a mass storage. If a **USB** storage device is inserted, the instrument uses the USB as mass storage. If no USB storage device is inserted, the instrument uses a DVD disk as mass storage.

Table E-5 Media area

For information on mass storage media, see *Data storage* on page B-244.

File Name Enter a file name (1 to 8 characters) in the text box.

Reports

Several reports are generated from the system. This chapter contains examples of the various reports and discusses their content and use. The date and time the report was printed is displayed in the upper right hand corner of each report.

Some reports, such as the **Calibration Monitor** report, are printed automatically by the system, whereas others are selected manually from the global **Print** screen. To toggle the automatic generation of reports, choose **Utility** > **System** (**Page 4/4**) > **Automatic Printout** and select the respective item.

See *Automatic Printout Setting window* on page E-418.

Area	Name	Printed From	Page
Workplace	Data Monitor/Report	Print > Workplace	E-77
	Reaction Monitor		E-84
	Requisition List	Print > Workplace	E-88
	Rerun List	Print > Workplace	E-92
	Precision Check	Print > Workplace	E-95
	Profile List	Print > Workplace	E-97
	Emergency Sample Monitor	Automatic Printout (activated on Utility > System (Page 4/4) > Automatic Printout)	E-418
Reagent Information	Reagent Status	Print > Reagent	E-99
	Reagent Load/Unload List	Print > Reagent	E-104
Calibration	Reaction Monitor		E-107
	Calibrator Load List	Print > Calibration	E-109
	Calibration Trace	Print > Calibration	E-111
	Calibration Result		E-117
	Calibration Request List	Print > Calibration	E-119
	Calibration Monitor	Automatic Printout (Activated on Utility > System (Page 4/4) > Automatic Printout)	E-121
QC	Individual QC Chart		E-129
	Individual QC List	Print > QC	E-135
	Cumulative QC Chart	Print > QC	E-138
	Cumulative QC List	Print > QC	E-142
	QC Load List	Print > QC	E-144
	QC Request List	Print > QC	E-147
	Control Result Monitor	Automatic Printout (Activated on Utility > System (Page 4/4) > Automatic Printout)	E-77

Table E-6 Available reports (Sheet 1 of 2)

Area	Name	Printed From	Page
Utility	Alarm Trace	Print > Utility	E-149
	Communication Trace	Print > Utility	E-154
	Operator ID Trace	Print > Utility	E-156
	Cumulative Operations List	Print > Utility	E-158
	Application Parameters	Print > Utility	E-161
	Report Example	Print > Utility	E-163
	Cell Blank		E-165
	Maintenance Report	Print > Utility	E-167
	Cuvette History		E-171
	Rack Archival Report		E-175
Automatic Maintenance Printouts View	Hard Disk Check report	View	E-179
	Backup Disk report	View	E-182
	Mass Storage report	View	
	Barcode Reader Check report	View	E-184
	Sample Barcode Reader Check report	View	E-184
	Reagent Barcode Reader Check report	View	E-185
	Liquid Short Sensor Check report	View	
Automatic Printouts	Calibration Monitor report	Automatically	E-121
	ISE Calibration Monitor report	Automatically	E-121
	Photometric Monitor report	Automatically	E-123
	Immunology Monitor report	Automatically	E-125
	Control Result Monitor report	Automatically	E-418
	Sample report	Automatically	E-77

Table E-6 Available reports (Sheet 2 of 2)

Workplace print screen

➔ **Print** (global button) > **Work Place**

The **Print > Work Place** screen displays a list of reports relating to the **Workplace** menu. The screen changes depending on the report selected and whether the system is in barcode mode or non-barcode mode.

Data Monitor/Report

➔ **Print** (global button) > **Work Place** > **Data Monitor/Report**

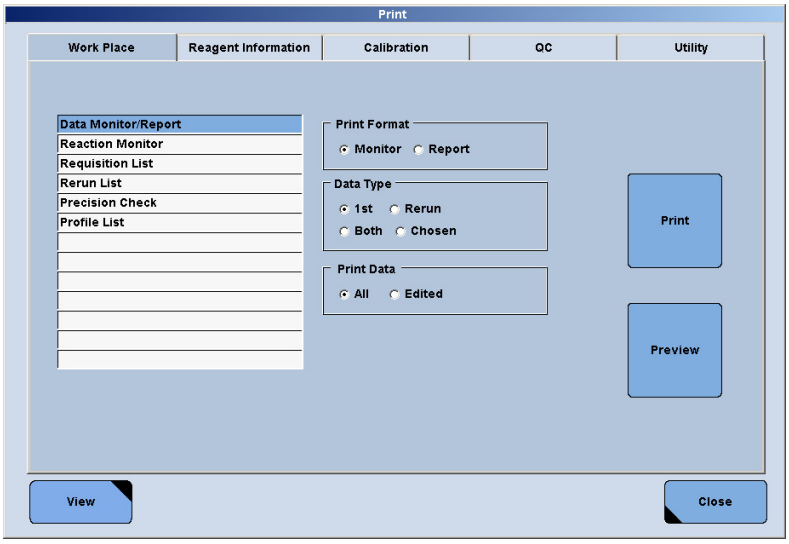


Figure E-44 Data Monitor/Report screen

Prior to printing or viewing this report, select the desired data on **Workplace** > **Data Review**.

Select **Data Monitor/Report** in the report list to print the measured data for the selected samples.

For detailed instructions, see *Printing sample information* on page B-72.

For information on the tabs, see *Print screen* on page E-68.

Print Format area

Monitor Select **Monitor** to print the report in the short format.

Report Select **Report** to print the report in the long or chartable format.

Results with exception data alarms (**Utility** > **System** (**Page 4/4**) > **Review By Exception**) are not printed in the report format.

For information on exception data alarms, see *Review By Exception window* on page E-419.

Data Type area

1st Select **1st** to print the report for the first run results.

Rerun Select **Rerun** to print the report for the rerun results.

Both Select **Both** to print the report for both the first run and the rerun results.

Chosen Select **Chosen** to print the report for the chosen results. In case two results are available for one test, it is possible to mark the one which should be printed out. This can be done in **Test Review** window by choosing the box in the first column of the first or second result.

See *Test Review window* on page E-232.

Print Data area

All Select **All** to print all results, including edited results.

Edited Select **Edited** to print only the edited results.

Buttons

Print Choose this button to send the selected report to the printer and to store it in the print buffer.

Preview Choose **Preview** and then **View** to display a preview of the currently selected report without printing the report.

View Choose this button to view the lists and reports currently in the print buffer and also to write them to disk.

For more information, see:
Print View window on page E-70
Media Write window on page E-74

Data Monitor report (monitor format)

```
                                  Data Monitor                        09/10/09        14:03

Ser/Pl      N          00003-2                  000208
09/10/09              CA (C)       GLUC2 (C)        ASTL (C)          Na (C)           K (C)
12:15:44             1.96            8.01             8.1              82            3.63
   admin

                    MYO (E-1)       TSH (E-2)           CK-MB       FT4
                   21,00           0.635                1.69      14.09
                   <Test
```

Figure E-45 Data Monitor report (monitor format)

Data Monitor report (monitor format) explanation

Date, Time The date and time the report was printed appears to the right of the report name.

Sample data The sample data in the first line below the report title consists of the Sample Type, Rack Type, Rack No.-Pos., and the Sample ID.

This information is manually entered on **Workplace** > **Test Selection** or is transferred from the Host.

See *Test Selection screen* on page E-203.

Sample Type This field displays the type of sample material (for example, Ser/Pl, Urine).

Rack/Run Type This field displays the type of rack (Routine or STAT) and type of run (first run or rerun).

N	Routine (normal) sample
E	STAT (emergency) sample
C	Control sample
NR	Rerun of routine sample
ER	Rerun of STAT sample

In barcode mode, only the code is displayed. In non-barcode mode the sequence number is attached to the code.

Rack No.-Pos.(XXXXX-X) This field displays the rack number (first 5 digits) and the position of the sample tube in the rack (last digit). For control samples this field displays the control number defined on **QC** > **Install** plus the sequence number.

Sample ID This field displays the sample identification.

Date, Time The date and time when the sample was registered by the analyzer is displayed below the sample type.

Pre-diluted If a sample has been pre-diluted, a P is printed to the left of the Operator ID.

Operator ID The operator ID at the time the tests were run is displayed below date and time if operating in password protection mode.

Results Printout

Each page can display results of multiple patient samples.

The Results Printout includes Test name, Result and Data alarm.

Test name

The short test name of the application is displayed. To the right of the test name, the name of the module and measuring channel (**e** 601 module) is displayed, on which the test was performed (only if **Print Module ID** is enabled under **Utility** > **System** > **Analyzer Setting** area).

Result

The result of the test is displayed below the test name. H (high) or L (low)—printed to the right of the result—indicates that this result is outside the expected range.

Increased (Inc), decreased (Dec) or the dilution ratio is printed to the right of the result.

Test results print in the order defined under **Utility** > **Report Format** > **Print Order**.

For qualitative assays (**e** 601 module) reac. or n-reac. is displayed depending on whether the result is inside or outside the Cutoff Index.

The qualitative result display (**c** 501 module) is configured in the **Qualitative** area under **Utility** > **Application** > **Range**.

See *Expected Values area* on page E-506.

Data alarm

Data alarms are printed below the test result.

Samples with data alarms that trigger a rerun are placed on the rerun list and automatically rerun if automatic rerun is selected.

For more information on the rerun list, see:
Rerun List on page E-92
Rerun list on page D-63

Reagent status

For QC samples only, the status of the reagent (**Current** or **Stand by**) is printed to the right of the test name (only if **Reagent Information Printout** is enabled under **Utility** > **System** (1/4)> **QC Setting**).

Lot/Sequence number or Position

For QC samples only, the lot and sequence number of the reagent is displayed below the reagent status.

For ISE reagents (ISE IS), the position of the bottle is displayed (Pos. 1 or Pos. 2). (Only if **Reagent Information Printout** is enabled under **Utility** > **System** (1/4)> **QC Setting**).

Data Monitor report (report format)

```
                        ******************************************
                        *          HITACHI AUTOMATIC ANALYZER    *
                        ******************************************

ID                                  000434 DATE         18/09/08    17:05:23
S.NO.             N       00014-2          OPERATOR ID       admin
S.TYPE            Ser/Pl                   Name
AGE
SEX
DRAW DATE
DRAW TIME
PREDILUTED        NO
TEST              RATIO   COI/MES    RESULT  UNIT        MODULE       EXPECTED VALUE    ALARM
TOTAL PROTEIN                          49.6  g/dL        C            ( -99999- 999999)
Chol                                    174  mg/dL       C            ( -99999- 999999)
Crea                                   1.18  mg/dL       C            ( -99999- 999999)
Na                                      125  mmol/L      C            ( -99999- 999999)
K                                       3.5  mmol/L      C            ( -99999- 999999)
Cl                                       87  mmol/L      C            ( -99999- 999999)
ALB                                      33  g/L         C            ( -99999- 999999)
```

Figure E-46 Data Monitor report (report format)

Data Monitor report (report format) explanation

The format of this report can be configured under **Utility** > **Report Format**.

See *Report Format screen* on page E-540.

The information for patient data (like ID, S.NO., etc.) is manually entered on **Workplace** > **Test Selection** or is transferred from the Host.

See *Test Selection screen* on page E-203.

Results with exception data alarms (**Utility** > **System** (**Page 4/4**) > **Review By Exception**) are not printed in the report format.

For information on exception data alarms, see *Review By Exception window* on page E-419.

Report title The title is displayed at the top of the report.

ID This field displays the patient identification.

DATE The date and time when the sample was registered by the analyzer is displayed on the right of the ID.

S.NO. The sample number consists of the Rack Type and Rack No.-Pos.

Rack/Run Type This field displays the type of rack (Routine or STAT) and type of run (first run or rerun).

N	Routine (normal) sample
E	STAT (emergency) sample
NR	Rerun of routine sample
ER	Rerun of STAT sample

In barcode mode, only the code is displayed. In non-barcode mode the sequence number is attached to the code.

Rack No.-Pos.(XXXXX-X) This field displays the rack number (first 5 digits) and the position of the sample tube in the rack (last digit).

OPERATOR ID The operator ID at the time the tests were run is displayed below date and time if operating in password protection mode.

S. TYPE This field displays the type of sample material (for example, Ser/Pl, Urine).

Comment This field displays the text entered in the **Main Comment** field (for example Name) on the **Demographics** window.

See:
Demographics window on page E-211
Comment Title window on page E-383

AGE This field displays the patient age.

SEX This field displays the patient sex.

DRAW DATE This field displays the date the sample was drawn from the patient.

DRAW TIME This field displays the time the sample was drawn from the patient.

PRE-DILUTED This field displays **YES** if the sample has been pre-diluted or **NO** if no pre-dilution has been performed.

Results Printout The results are displayed in a table. The results are listed in the order defined under **Utility** > **Report Format** > **Print Order**.

The table consists of the following columns:

TEST This field displays the report name of the application.

RATIO This field displays the dilution ratio or if an increased (Inc) or decreased (Dec) sample concentration was used.

COI/MES This field displays the cutoff index for **e** 601 qualitative assays.

RESULT This field displays the test result. H (high) or L (low)—printed to the right of the result—indicates that this result is outside the expected range.

For qualitative assays (**e** 601 module) reac. or n-reac. is displayed depending on whether the result is inside or outside the Cutoff Index.

The qualitative result display (**c** 501 module) is configured in the **Qualitative** area under **Utility** > **Application** > **Range**.

See *Expected Values area* on page E-506.

UNIT This field displays the unit of measure for the listed result.

MODULE This field displays the name of the module and measuring channel on which the test was performed.

EXPECTED VALUE This field displays the expected values for the results of the test.

ALARM This field displays the data alarm for the test.

Samples with data alarms that trigger a rerun are placed on the rerun list and automatically rerun if automatic rerun is selected.

See *Rerun List* on page E-92.

For more information about data alarms that trigger a rerun, see *Rerun list* on page D-63.

Reaction Monitor

➔ **Print** (global button) > **Work Place** > **Reaction Monitor**

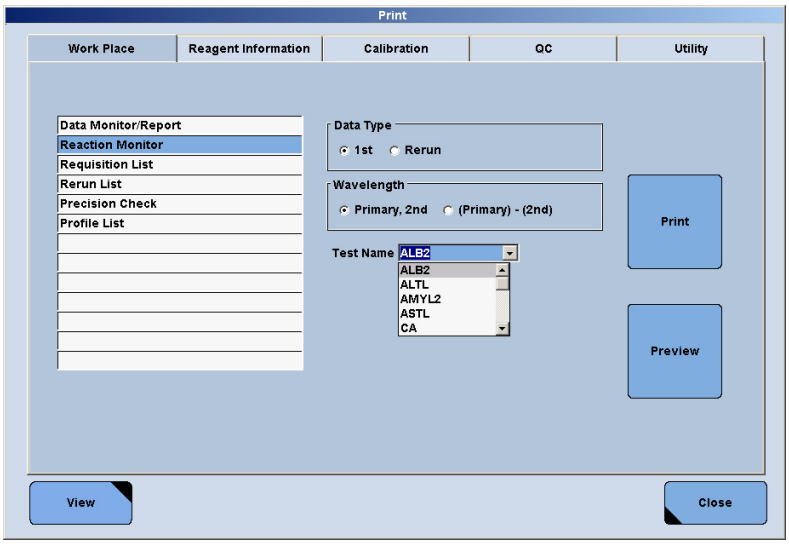


Figure E-47 Reaction Monitor print screen

Select **Reaction Monitor** in the report list to print the **Reaction Monitor** report for the selected samples.

Prior to printing or viewing this report, select the desired data on **Workplace** > **Data Review**.

This report is only available for **c** 501 (P) tests.

For information on the tabs, see *Print screen* on page E-68.

Test Name Select the desired test for the report from the list box.

Data Type area

1st Select **1st** to print the report for the first run results.

Rerun Select **Rerun** to print the report for rerun results.

Wavelength area

Primary, 2nd Select **Primary, 2nd** to print the primary and secondary wavelength data.

(Primary) - (2nd) Select **(Primary) - (2nd)** to print the difference of the primary wavelength data less the secondary wavelength data.

Buttons

Print Choose this button to send the selected report to the printer and to store it in the print buffer.

Preview Choose **Preview** and then **View** to display a preview of the currently selected report without printing the report.

View Choose this button to view the lists and reports currently in the print buffer and also to write a report to disk.

For more information, see:
Print View window on page E-70
Media Write window on page E-74

Reaction Monitor report

Reaction Monitor report for **c** 501 modules

```
                              Reaction Monitor            29/05/08  15:29

Ser/Pl    N000002   00007-1   29/05/08  C         CELL      095   CA  3.70
ID 0002                       09:04:44

***  PRIMARY  ***
    CB1-3      1-10     11-20     21-30     31-40     41-50     51-60     61-70
     8423       488      4948      4749      4738      4746      4741      4740
     8425       404      4826      4744      4743      4752      4742      4732
     8424       356      4774      4743      4739      4744      4745      4732
                327      4768      4745      4745      4743      4740      4730
                325      4764      4741      4739      4738      4744      4737
                317      4765      4737      4745      4744      4743      4733
                314      4759      4740      4747      4741      4740      4733
                311      4752      4742      4746      4742      4746      4727
                291      4748      4742      4742      4743      4748      4727
                288      4750      4735      4739      4742      4740      4724

***  SECONDARY  ***
    CB1-3      1-10     11-20     21-30     31-40     41-50     51-60     61-70
     8810       374       138       134       134       142       142       152
     8811       303       175       131       136       146       142       147
     8811       258       132       131       135       141       145       148
                235       130       134       139       142       143       148
                235       132       131       135       136       145       155
                229       135       130       140       139       146       154
                225       133       134       141       138       145       155
                226       132       135       141       140       151       154
                208       130       135       136       140       154       150
                206       133       130       135       140       149       151
```

Figure E-48 Reaction Monitor report

Reaction Monitor report for bichromatic measurements on **c** 501 modules

```
                              Reaction Monitor                          29/05/08  15:30

Ser/Pl    N000002   00007-1   29/05/08  C         CELL      095   CA  3.70
ID 0002                       09:04:44

***  (PRIMARY) - (SECONDARY)  ***
    CB1-3      1-10     11-20     21-30     31-40     41-50     51-60     61-70
     -387       114      4810      4615      4604      4604      4599      4588
     -386       101      4651      4613      4607      4606      4600      4585
     -387        98      4642      4612      4604      4603      4600      4584
                 92      4638      4611      4606      4601      4597      4582
                 90      4632      4610      4604      4602      4599      4582
                 88      4630      4607      4605      4605      4597      4579
                 89      4626      4606      4606      4603      4595      4578
                 85      4620      4607      4605      4602      4595      4573
                 83      4618      4607      4606      4603      4594      4577
                 82      4617      4605      4604      4602      4591      4573
```

Figure E-49 Reaction Monitor report for bichromatic measurements

Reaction Monitor report explanation

Date, Time The date and time the report was printed appears to the right of the report name.

Sample data The sample data consists of the Sample Type, Rack Type, Rack No.-Pos., and the Sample ID.

This information is manually entered on **Workplace** > **Test Selection** or is transferred from the Host.

See *Test Selection screen* on page E-203.

Sample Type This field displays the type of sample material (for example, Ser/Pl, Urine).

Rack/Run Type This field displays the type of rack (Routine or STAT) and type of run (first run or rerun).

N	Routine (normal) sample
E	STAT (emergency) sample
NR	Rerun of routine sample
ER	Rerun of STAT sample

In barcode mode, only the code is displayed. In non-barcode mode the sequence number is attached to the code.

Rack No.-Pos. (XXXXX-X) This field displays the rack number (first 5 digits) and the position of the sample tube in the rack (last digit).

An "*" next to the sample number indicates that the sample was in a micro cup or micro cup on a tube when it was processed

Sample ID (ID) This field displays the patient identification.

Comment This field displays the text entered in the **Main Comment** field (for example Name) on the **Demographics** window.

For more information on the **Main Comment** field, see:
Demographics window on page E-211
Comment Title window on page E-383

Date, Time The date and time when the sample was registered by the analyzer is displayed below the sample type.

Module ID This field displays the name of the module on which the test was performed. Analytical modules include only **c** 501.

CELL This field displays the reaction cell that contained the chemical reaction whose results are displayed on the report.

Test 1 name and result The test name and the calculated result appear to the right of the cell number. If a data alarm exists, it appears to the right of the numeric result.

Test 2 name and result If a second test was run within the same cell, the test name and result (as well as any existing data alarms) appear in parentheses to the right of the first test name and results.

**** PRIMARY ****
**** SECONDARY ****
(PRIMARY) - (SECONDARY) Absorbance data points are printed for the specified sample number. The first line gives the cycle number during which the readings occurred. The first column contains the cell blank readings (CB1-3), either primary, secondary, or primary minus secondary (bichromatic) wavelengths. The other columns contain the reaction absorbencies obtained with each pass through the photometer read window.

Requisition List

➔ **Print** (global button) > **Work Place** > **Requisition List**

The screen varies depending on how you access it. If you first selected a sample(s) on **Workplace** > **Data Review**, the screen appears with no additional enterable fields.

If you access from anywhere else in the system software, the Requisition List print screen (barcode mode) or the Requisition List print screen (non-barcode mode) is displayed, depending on whether the system is in barcode mode or non-barcode mode.

👁 For more information, see:
Requisition List print screen (barcode mode) on page E-88
Requisition List print screen (non-barcode mode) on page E-89

Requisition List print screen (barcode mode)

➔ **Print** (global button) > **Work Place** > **Requisition List**

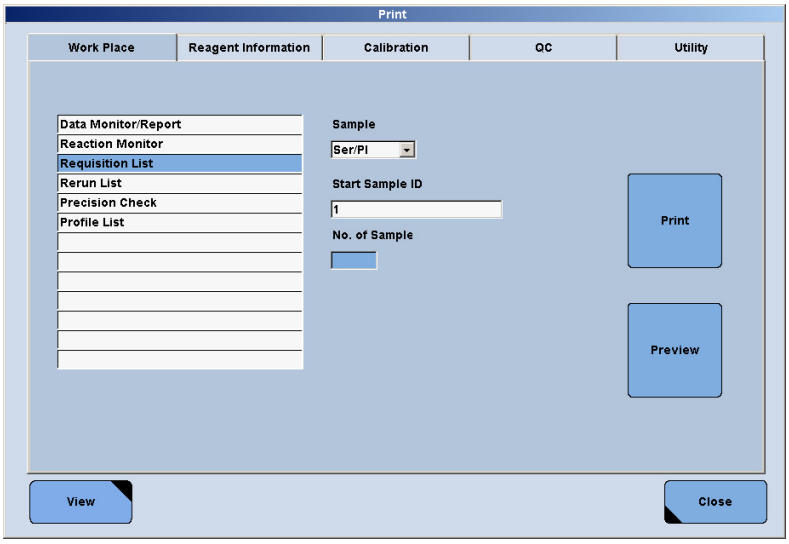


Figure E-50 Requisition List print screen (barcode mode)

Select **Requisition List** from the report list to print the report for the specified samples.

👁 For information on the tabs, see *Print screen* on page E-68.

Sample Select the sample type from the list box to print the requisition list for the specified sample type.

Start Sample ID Use this text box to specify the first ID number to be printed on the requisition list.

No. of Samples Use this text box to specify the number of samples (1-10,000) to be printed on the requisition list.

👁 See Buttons.

Requisition List print screen (non-barcode mode)

➔ **Print** (global button) > **Work Place** > **Requisition List**

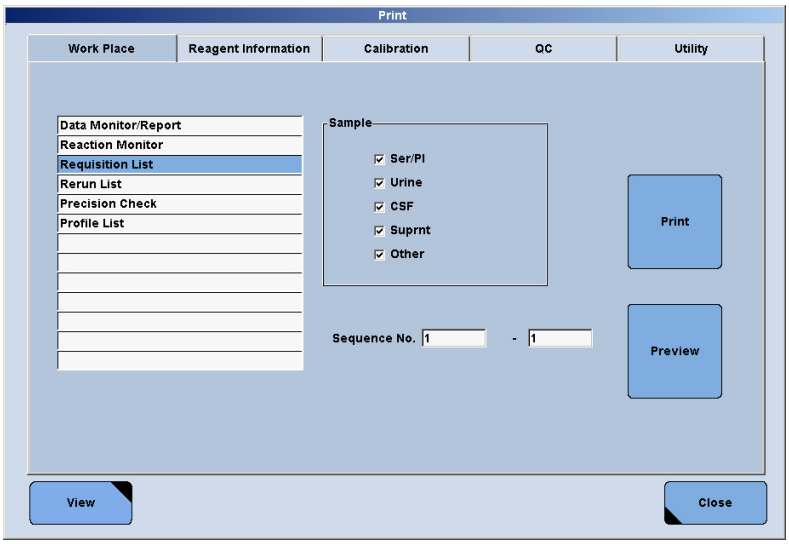


Figure E-51 Requisition List print screen (non-barcode mode)

Select **Requisition List** from the report list to print the report for all samples specified by Sequence No.

For information on the tabs, see *Print screen* on page E-68.

Sample area Select the desired check box(es) to print the requisition list for samples of the selected type(s).

Sequence No. Type the range of sample numbers to be printed. Type the first number of the range (1 to 60,000) in the first text box and press <Enter>. Type the last number of the range (1 to 60,000) in the last text box and press <Enter>. The database holds up to 10,000 records, which can be numbered from 1 to 60,000.

See Buttons.

Buttons

Print Choose this button to send the selected report to the printer and to store it in the print buffer.

Preview Choose **Preview** and then **View** to display a preview of the currently selected report without printing the report.

View Choose this button to view the lists and reports currently in the print buffer and also to write them to disk.

For more information, see:
Print View window on page E-70
Media Write window on page E-74

Requisition List report

```
                    Requisition List                          04/12/08    19:05

      ID            S.TYPE   COMMENTS                         S.CUP
                    90001  Ser/Pl                             Micro
   AMY-P                  Cl    CREP2                CRPLX        GGTI2
   GLUC2                   K       MG                   Na         S-CA
   SCRE2                TRIGL
                    90002  Ser/Pl
   AMY-P                CK-MB       Cl                GGTI2        GLUC2
   GLUC3              HCG-BETA       K                   Na         S-CA
   TRIGL
                    90003  Ser/Pl
     B12                CHO2I       Cl                GLUC3            K
     MYO (  2)             Na    SCRE2                  UA2
                    90004  Ser/Pl
   CHO2I                  Cl    GLUC3              HCG-BETA            K
     MYO (  2)             Na     TN-T                  UA2
                    90005  Ser/Pl
     B12                  CA    CHO2I                   Cl          FT4
   GGTI2                GLUC2 HCG-BETA                   K           Na
   PHOS2                S.IND    TRIGL

---------------------           TEST COUNT           ---------------------------------
TEST        COUNT      TEST        COUNT      TEST        COUNT      TEST        COUNT
A1-W2           0      CK-MB           1      HB-W2           0      RWI2            0
ALB2            0      Cl              5      HCG-BETA        3      S-CA            2
ALBS2           0      CREP2           1      IRON2           0      SCRE2           2
ALTL            0      CRPLX           1      K               5      T4              0
ASTLP           0      FT4             1      MG              1      TN-T            1
B12             2      GGTI2           3      MYO             2      TRIGL           3
CA              1      GLUC2           3      Na              5      UA2             2
CHO2I           3      GLUC3           3      PHOS2           1      S.IND           1
```

Figure E-52 Requisition List report

Requisition List report explanation

Date, Time The date and time the report was printed appears to the right of the report name.

Sample data The sample data consists of the Sample number (S.NO), ID, and the Sample Type.

This information is manually entered on **Workplace** > **Test Selection** or is transferred from the Host.

See *Test Selection screen* on page E-203.

S.NO (non-barcode mode only) This field displays the type of rack (Routine or STAT) and type of run (first run or rerun).

N	Routine (normal) sample
E	STAT (emergency) sample
NR	Rerun of routine sample
ER	Rerun of STAT sample

The sequence number is attached to the code.

ID This field displays the patient identification.

S.TYPE This field displays the type of sample material (for example, Ser/Pl, Urine).

Pre-diluted If a sample has been pre-diluted, a P is printed to the left of the Sample data information.

COMMENTS This field displays the text entered in the **Main Comment** field (for example Name) on the **Demographics** window.

For more information on the **Main Comment** field, see:
Demographics window on page E-211
Comment Title window on page E-383

S.CUP This column displays if a microcup has been programmed for this sample.

Restrictions for the use of micro cups

When the end of sample probe touches the inner wall of a micro cup this may result in improper sample aspiration.

- Do not use micro cups on **e** 601 modules.
- Do not use micro cups for calibrators and controls.

Test Names The tests selected for the specific patient are listed horizontally below the identification line. Tests are listed in alphabetical order.

The dilution ratio or increased/decreased sample concentration is displayed to the right of the test name.

- For example a dilution ratio of 1:5 is displayed as (5)
- Increased sample concentration is displayed as (Inc)
- Decreased sample concentration is displayed as (Dec)

TEST COUNT The TEST COUNT table displays the total number of requests per test for the selected samples.

The table consists of up to 4 pairs of columns. Each pair of columns includes the short name of the test (TEST) and the total number of requests (COUNT).

Rerun List

➔ **Print** (global button) > **Work Place** > **Rerun List**

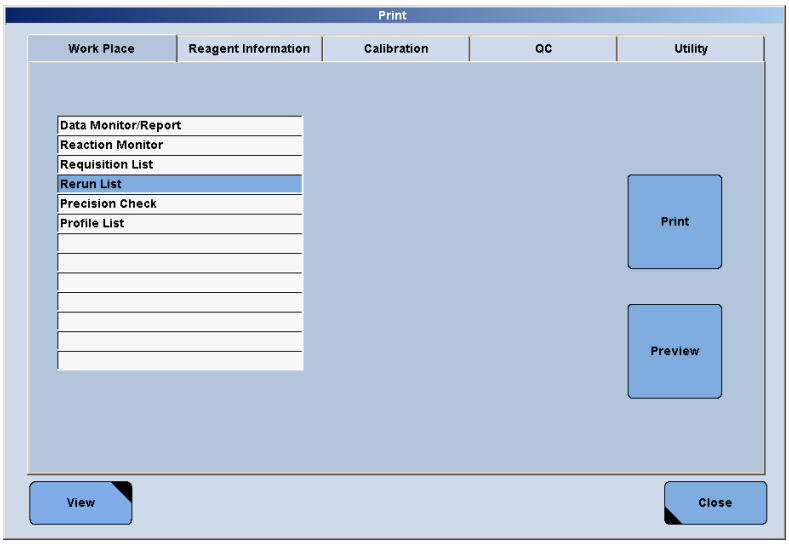


Figure E-53 Rerun List print screen

Prior to printing or viewing this report, select the desired data on **Workplace** > **Data Review**.

Select **Rerun List** in the report list to print the **Rerun List** report for the selected samples.

For information on the tabs, see *Print screen* on page E-68.

Buttons

Print Choose this button to send the selected report to the printer and to store it in the print buffer.

Preview Choose **Preview** and then **View** to display a preview of the currently selected report without printing the report.

View Choose this button to view the lists and reports currently in the print buffer and also to write them to disk.

For more information, see:
Print View window on page E-70
Media Write window on page E-74

Rerun List report

```
                                Rerun List                          15/05/08        09:30

S.NO        R.NO.                   ID                      S.TYPE      S.CUP
  COMMENTS
NR          00020-2                             1234522

            ALB2(Dec)                 Na
            >Test                   >Test

---------------------------------------- TEST COUNT -----------------------------------
TEST        COUNT       TEST        COUNT       TEST        COUNT       TEST        COUNT
ALB2             1      CHO2A            0      HCG-BETA         1      SI               0
ALTL             0      CL               0      K                0      TP2              0
AMYL2            0      CREAJ            0      LDH              0      TSH              0
ASTL             0      GGTI2            0      MG               0      S.IND            0
CA               0      GLUC2            0      NA               1
```

Figure E-54 Rerun List report

Rerun List report explanation

The **Rerun List** shows the samples and tests scheduled to be rerun.

Samples with data alarms that trigger a rerun are placed on the **rerun list** and automatically rerun if automatic rerun is selected.

Individual sample information is displayed on the top of the rerun list and the **Rerun List** test count is displayed on the bottom.

For more information about data alarms that trigger a rerun, see *Rerun list* on page D-63.

Date, Time The date and time the report was printed appears to the right of the report name.

Sample data The following Sample data is displayed on this report: Sample number (S.NO), Rack number and -position (R.NO.), Sample ID (ID), Sample type (S.TYPE), Sample cup (S.CUP) and COMMENTS.

This information is manually entered on **Workplace** > **Test Selection** or is transferred from the Host.

See *Test Selection screen* on page E-203.

S.NO This field displays the type of rack (Routine or STAT) and type of run (in this report only rerun).

NR	Rerun of routine sample
ER	Rerun of STAT sample

In barcode mode, only the code is displayed. In non-barcode mode the sequence number is attached to the code.

R.NO. (XXXXX-X) This field displays the rack number (first 5 digits) and the position of the sample tube in the rack (last digit).

ID This field displays the patient identification.

S.TYPE This field displays the type of sample material (for example, Ser/Pl, Urine).

S.CUP This column displays if a micro cup has been programmed for this sample.

Restrictions for the use of micro cups

When the end of sample probe touches the inner wall of a micro cup this may result in improper sample sucking.

- Do not use micro cups on **e** 601 modules.
- Do not use micro cups for calibrators and controls.

Pre-diluted If a sample has been pre-diluted, a P is printed to the left of the Sample data information.

COMMENTS This field displays the text entered in the **Main Comment** field (for example Name) on the **Demographics** window.

For more information on the **Main Comment** field, see:
Demographics window on page E-211
Comment Title window on page E-383

Test Names The tests selected for the specific patient are listed horizontally below the identification line. Tests are listed in alphabetical order.

The dilution ratio or increased/decreased sample concentration is displayed to the right of the test name.

- For example a dilution ratio of 1:5 is displayed as (5)
- Increased sample concentration is displayed as (Inc)
- Decreased sample concentration is displayed as (Dec)

The data alarm that occurred on the first run and triggered the rerun is displayed below the test name.

TEST COUNT The TEST COUNT table displays the total number of requests per test for the selected samples.

The table consists of up to 4 pairs of columns. Each pair of columns includes the short name of the test (TEST) and the total number of requests (COUNT).

Precision Check

➔ **Print** (global button) > **Work Place** > **Precision Check**

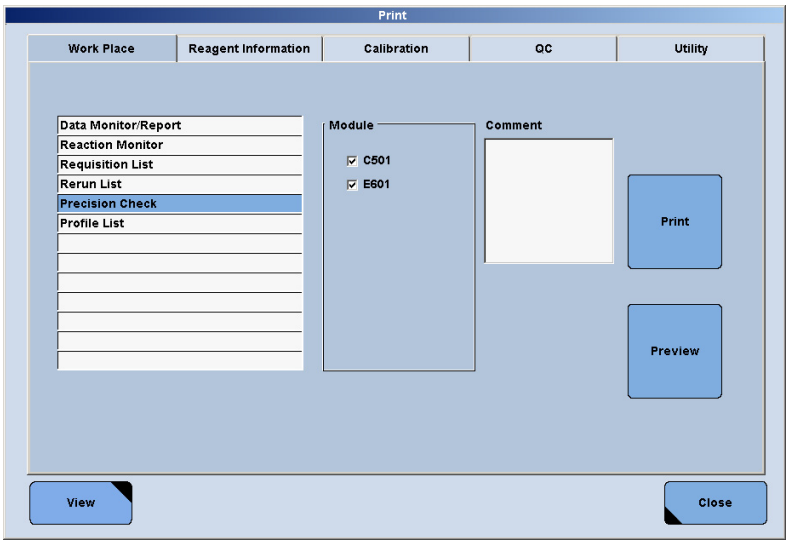


Figure E-55 Precision Check print screen

Select **Precision Check** from the report list to print the report for the selected samples. This report can be used to troubleshoot application problems or verify precision, particularly after performing maintenance.

Prior to printing or viewing this report, select the desired data on **Workplace** > **Data Review**.

For information on the tabs, see *Print screen* on page E-68.

Module Select the desired module(s) for the precision check report.

Comment Type a comment with up to 80 characters.

Buttons

Print Choose this button to send the selected report to the printer and to store it in the print buffer.

Preview Choose **Preview** and then **View** to display a preview of the currently selected report without printing the report.

View Choose this button to view the lists and reports currently in the print buffer and also to write them to disk.

For more information, see:
Print View window on page E-70
Media Write window on page E-74

Precision Check report

```
                                Precision Check                  21/10/08        15:46

                     after service


MODULE    C
  TEST        N          MEAN    UNIT          RANGE    MAX.    MIN.      SD     CV(%)
  CA      00021         1.020    mmol/L         0.08    1.04    0.96   0.019      1.85
  Cl      00021         49.83    mmol/L          1.0    50.2    49.2    0.28      0.57
  K       00021         2.489    mmol/L         0.05    2.51    2.46   0.013      0.52
  Na      00021          62.5    mmol/L            3      64      61     0.7      1.20
  TP2     00021         51.54    g/L             2.7    52.6    49.9    0.63      1.22
```

Figure E-56 Precision Check report

Precision Check report explanation

Comment The comments entered on the **Precision Check** print screen appear just below the report title. If no comment is entered on the **Precision Check** print screen, nothing is printed here.

Date, Time The date and time the report was printed appears to the right of the report name.

MODULE This field displays the module and measuring channel (**e** 601 module) on which the test was performed.

TEST This column displays the tests of the selected samples. Results with data alarms are excluded from the calculation.

N This column displays the number of results considered for calculating the statistics.

MEAN This column displays the calculated mean for each test.

UNIT This column displays the unit of measure for each test.

RANGE This column displays the difference between the highest and lowest results for each test.

MAX. This column displays the maximum value for each test.

MIN. This column displays the minimum value for each test.

SD This column displays the calculated standard deviation for each test.

CV(%) This column displays the calculated coefficient of variation (CV) for each test.

Results with a flag are not included in the precision check statistics

Profile List

➔ **Print** (global button) > **Work Place** > **Profile List**

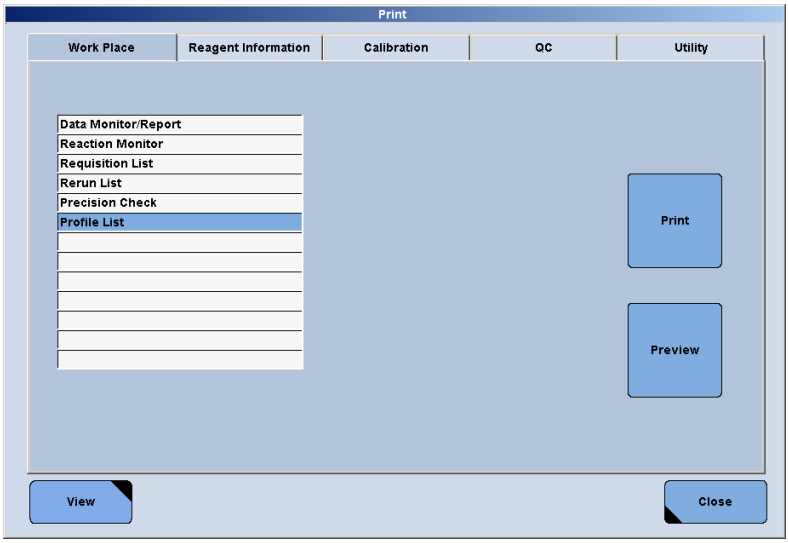


Figure E-57 Profile List print screen

Select this item from the report list to print the **Profile List** report. The **Profile List** contains the names of each profile and the tests assigned to each profile programmed on the system.

For information on the tabs, see *Print screen* on page E-68.

Buttons

Print Choose this button to send the selected report to the printer and to store it in the print buffer.

Preview Choose **Preview** and then **View** to display a preview of the currently selected report without printing the report.

View Choose this button to view the lists and reports currently in the print buffer and also to write them to disk.

For more information, see:
Print View window on page E-70
Media Write window on page E-74

Profile List report

```
                                  Profile List                    21/10/08    17:59

***         Ser/Pl           ***
          2    Profile1      Cl       GLUC3    K        Na       T4       TN-T      UA2
          3    e601          FT4      MYO
          4    ISE/Ser       Cl       K        Na
          5  # Demorun       ASTLP    CK-MB    Cl       GLUC2    K        MG        MYO
                             Na
          6  * super ju      CA       Cl       GLUC2    K        Na       TP2

***         Urine            ***
          1    ISE           Cl       K        Na
```

Figure E-58 Profile List report

For more information, see *Assigning tests or profiles to test keys* on page B-281.

Profile List report explanation

Date, Time The date and time the report was printed appears to the right of the report name.

Profile Name The first column displays the name of each profile. An asterisk (*) to the left of the profile name indicates a routine default profile. A pound sign (#) to the left of the profile name indicates a STAT default profile.

Test Name The short test name of each test in a profile is displayed in up to 7 columns from left to right.

Reagent Information print screen

➔ **Print** (global button) > **Reagent Information**

The **Reagent Information** print screen displays a list of reports relating to the **Reagent** menu. The screen changes depending on the report selected.

Reagent Status

➔ **Print** (global button) > **Reagent Information**

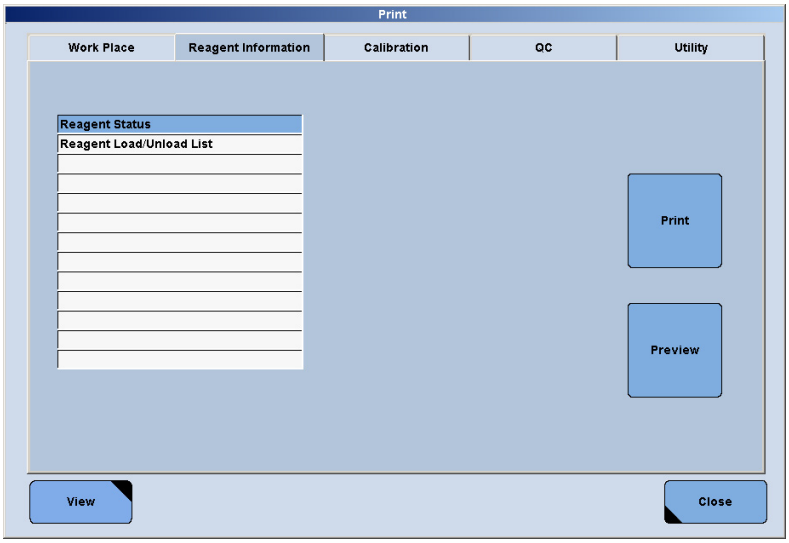


Figure E-59 Reagent Status print screen

Select **Reagent Status** from the report list to print a list which compiles all reagents and their status of the different analyzer modules including auxiliary reagents. No criteria need to be selected in order to print this report.

👁 For more information, see:
Reagents for ISE applications on page B-105
Reagents for photometric applications on page B-108
Reagents for immunoassay on page B-114
Replacing auxiliary reagents (c 501) on page B-131
Replacing auxiliary reagents (e 601) on page B-132

👁 For information on the tabs, see *Print screen* on page E-68.

Buttons

Print Choose this button to send the selected report to the printer and to store it in the print buffer.

Preview Choose **Preview** and then **View** to display a preview of the currently selected report without printing the report.

View Choose this button to view the lists and reports currently in the print buffer and also to write them to disk.

For more information, see:
Print View window on page E-70
Media Write window on page E-74

Reagent Status report

Reagent Status 21/10/08 18:01

TEST	MODULE	TYPE	POS.	TESTS		LOT	SEQ.	EXP.DATE	STAB.	
A-TPO	e1	ASSAY	14	75		00182536	045715	09/06	6	
A1-W2	C	ASSAY	20	150		695647	02250	09/03	21	
ALBS2	C	ASSAY	6	25		601443	09185	10/03	0	*
ALBU2	C	ASSAY	6	25		601443	09185	10/03	0	*
AMY-P	C	ASSAY	15	159		600200	02129	09/04	9	
ASTLP	C	ASSAY!	9	350		695048	02161	08/09*	0	*
B12	e1	ASSAY	3	81		00181823	175024	09/11	20	
		PRE	15	81		00181823	175704			
CA	C	ASSAY	28	265		696623	02500	08/12	14	
...										
...										
A1CD2	C	Dil	19	45	mL	693922	00766	09/03	21	
Dil Uni	e1	DIL	4	12	mL	00182247	025859	09/12	69	
NACL	C	Dil	16	38	mL	602339	03675	10/01	0	*
		Dil	31	39	mL	602339	03667	10/01	71	
		Dil	32	37	mL	602339	03673	10/01	0	*
NAOHD	C	D1	2	14	mL	604151	52183	10/05	65	
		D1	10	41	mL	601354	38726	10/03	80	
SMS	C	D2	1	41	mL	677232	00980	08/01*	0	*
		D2	4	41	mL	694198	03229	09/07	0	*
		D2	5	41	mL	677232	03940	08/01*	0	*
ISE	C	IS	1	390						
		IS	2	820						
		DIL	1	733						
		DIL	2	432						
		KCL	1	1933						
Inventory	C	CellCln	1	1594	mL					
		CellCln	2	1730	mL					
		SmpCln	1	54	mL					
		SmpCln	2	47	mL					
		Ecotergent		13	mL					
	e1	ProbeWash M	1	16	mL					
		ProbeWash M	2	39	mL					
		Magazine		4						
		MagWaste		8						
		ProCell	1	1986	mL	00000001				
		CleanCell	1	1986	mL					
		ProCell	2	179	mL	00000001				
		CleanCell	2	297	mL					
		PreCleanM!	1	448	mL					
		PreCleanM!	2	0	*mL					
		SolidWaste	1	1						
		SolidWaste	2	8						
		Tip		77						
		AssayCup		77						

Figure E-60 Reagent Status report

Reagent Status report explanation

Date, Time The date and time the report was printed appears to the right of the report name.

TEST This column displays the short test name of the reagent or the short name of the diluent and cleaner. For auxiliary reagents and consumables, Inventory is displayed.

- # is displayed to the right of the test name and to the right of the type of reagent when the reagent level is less than the Purple alarm level.
- ? is displayed to the right of the test name when the reagent level is zero.
- ! is displayed to the right of the type of reagent when the reagent level is less than the yellow alarm level.

MODULE This column displays the name of the module that contains the reagent.

TYPE This column displays the type of the reagent:

TYPE	Description	Module
ASSAY	Test	**c** 501 (P), **e** 601
PRE	Pretreatment	**e** 601
Dil	Diluent	**c** 501 (P)
DIL	ISE Dil.	**c** 501 (ISE)
DIL	Diluent	**e** 601
IS	Internal standard	**c** 501 (ISE)
KCL	Reference solution	**c** 501 (ISE)
D1	NaOH-D	**c** 501 (P)
D2	SMS	**c** 501 (P)
D3	SCCS	**c** 501 (P)

Table E-7 **Reagent status report**: **TYPE** column

For auxiliary reagents and consumables (Inventory) the short names used in the software are displayed.

If the remaining reagent volume falls below a warning level, the following flags are displayed to the right of the type:

- # is displayed when reagent level is less than the Purple alarm level.
- ! is displayed when reagent level is less than yellow alarm.
- ? is displayed when the reagent level is zero.

POS. This column displays the position number of the reagent, auxiliary reagent, or consumable.

An asterisk (*) to the right of the position indicates that an **e** 601 test has been manually registered.

TESTS This column shows the following information:

- For a **cobas c** pack or **cobas e** pack the number of remaining tests is displayed.
- For an ISE reagent, a cleaning solution or detergent the number of ml remaining is displayed.
- If a purple alarm level is set, it is printed in brackets.
- If the remaining reagent volume is zero, an asterisk (*) is displayed to the right of the number.
- For cleaner (D1, D2, D3) or diluent (Dil), an asterisk (*) is displayed when reagent level is less than 1 ml.

LOT This column displays the lot number of the **cobas c** pack or **cobas e** pack.

SEQ. This column displays the sequence number of the **cobas c** pack or **cobas e** pack. The sequence number is printed as serial number on the **cobas c** pack or **cobas e** pack.

For more information, see:
Setting screen on page E-251
Reagents on page B-108

EXP.DATE This column displays the expiration date of the **cobas c** pack or **cobas e** pack. The first 2 numbers represent the year, while the last 2 represent the month. If the reagent has already expired, the date is marked with an asterisk (*).

STAB. This column displays the number of days until the on board stability of the **cobas c** pack or **cobas e** pack expires. If the reagent has already expired, the date is marked with an asterisk (*).

Reagent Load/Unload List

➔ **Print** (global button) > **Reagent Information** > **Reagent Load/Unload List**

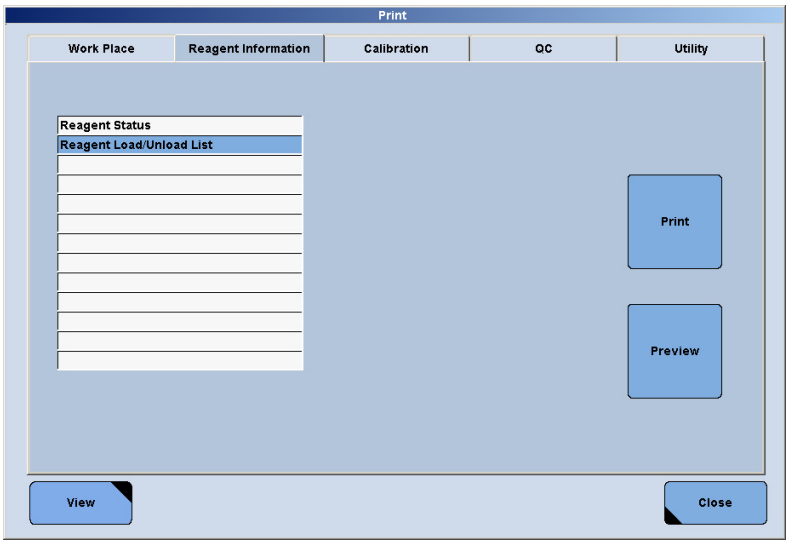


Figure E-61 Reagent Load/Unload List print screen

Select **Reagent Load/Unload List** from the report list to print a list which compiles all reagents that need to be loaded and those that need to be removed from the analyzer. No criteria need to be selected in order to print this report.

Reagent Load/Unload List

The **Reagent Load/Unload List** displays the reagents and the inventory loaded on the system including the number of tests remaining, any applicable reagent level alarm (purple, yellow or red) and any mandatory reagents that are not loaded. In addition the reagents currently loaded on the system that are not available for further tests and therefore need to be unloaded are displayed.

The **Reagent Load List** and the **Reagent Unload List** are printed on separate pages.

For information on the tabs, see *Print screen* on page E-68.

Buttons

Print Choose this button to send the selected report to the printer and to store it in the print buffer.

Preview Choose **Preview** and then **View** to display a preview of the currently selected report without printing the report.

View Choose this button to view the lists and reports currently in the print buffer and also to write them to disk.

For more information, see:
Print View window on page E-70
Media Write window on page E-74

Reagent Load/Unload List report

```
                    Reagent Load/Unload List (Load List)          21/10/08         18:01

OPERATOR ID : admin

------------------------------------ MODULE C          ----------------------------------------
TEST       REASON    TESTS           TYPE          POS.     TESTS    LOT         STAB.
ALB2       Yellow       12 (20)      ASSAY           21        12    688834        30
MG         Purple       10 (60)      ASSAY            6        10    691019         0

------------------------------------ MODULE E1         ----------------------------------------
TEST       REASON    TESTS           TYPE          POS.     TESTS    LOT         STAB.
Inventory  Yellow                    PreClean M       1       448 mL
           Yellow                    PreClean M       2         0 mL

                    Reagent Load/Unload List (Unload List)          21/10/08         18:01

OPERATOR ID : admin

------------------------------------ MODULE C          ----------------------------------------
     POS.  TEST      TYPE
       13  GLUC2     ASSAY
        1  ISE       DIL

------------------------------------ MODULE E1         ----------------------------------------
     POS.  TEST      TYPE
        2  Inventory PreClean M
        1  Inventory ProCell
```

Figure E-62 Reagent Load/Unload List

Reagent Load/Unload List report explanation

Date, Time The date and time the report was printed appears to the right of the report name.

OPERATOR ID This field displays the identification of the operator logged onto the analyzer when the printout was requested.

TEST This column displays the short test name of the reagent or the short name of the diluent and cleaner. **e** 601 auxiliary reagents and consumables are listed as Inventory.

REASON This column displays the reason, why the reagent has to be loaded or unloaded.

TESTS This column shows the following information:

- For a **cobas c** pack or **cobas e** pack the number of remaining tests is displayed.
- For an ISE reagent, a cleaning solution or detergent the number of ml remaining is displayed.
- If a Purple Alarm level is set, it printed in brackets.
- If a Yellow Alarm level is set, it printed in brackets.

TYPE This column displays the type of the reagent:

TYPE	Description	Module
ASSAY	Test	**c** 501 (P), **e** 601
PRE	Pretreatment	**e** 601
Dil	Diluent	**c** 501 (P)
DIL	ISE Dil.	**c** 501 (ISE)
DIL	Diluent	**e** 601
IS	Internal standard	**c** 501 (ISE)
KCL	Reference solution	**c** 501 (ISE)
D1	NaOH-D	**c** 501 (P)
D2	SMS	**c** 501 (P)
D3	SCCS	**c** 501 (P)

Table E-8 **Reagent status report**: **TYPE** column

For auxiliary reagents and consumables (Inventory) the short names used in the software are displayed.

If the remaining reagent volume falls below a warning level, the following flags are displayed to the right of the type:

For more information, see:
Reagents for ISE applications on page B-105
Reagents for photometric applications on page B-108
Reagents for immunoassay on page B-114

POS. This column displays the position number of the reagent, auxiliary reagent, or consumable.

TESTS This column displays the remaining number of ml or number of tests of the reagent. The second number in brackets represents the level set for the Purple Alarm.

LOT This column displays the lot number of the **cobas c** pack or **cobas e** pack.

STAB. This column displays the number of days until the corresponding **cobas c** pack or **cobas e** pack expires.

Calibration print screen

➔ **Print** (global button) > **Calibration**

The **Calibration Print** screen displays a list of reports relating to the **Calibration** menu. The screen changes depending on the report selected.

Reaction Monitor

➔ **Print** (global button) > **Calibration** > **Reaction Monitor**

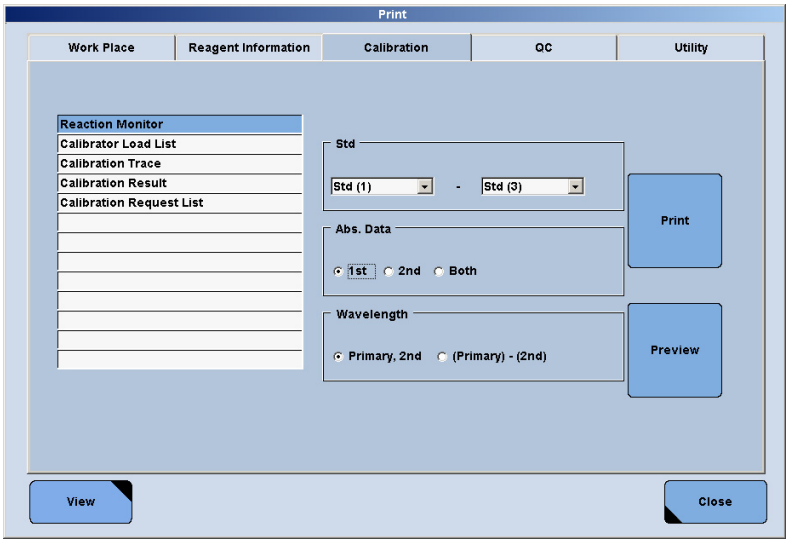


Figure E-63 Reaction Monitor print screen

Prior to printing or viewing this report, select the desired data for a **c** 501 test on **Calibration** > **Status**.

Select **Reaction Monitor** in the report list to print the **Reaction Monitor** report for the selected calibrations.

This report is not available for **e** 601 tests.

For information on the tabs, see *Print screen* on page E-68.

Standard area

Use these two list boxes to specify a standard range to be printed. Select Std (1) through Std (6) from the first list box and press <Enter>. Select Std (1) through Std (6) from the second list box and press <Enter>.

Abs. Data area

1st Select **1st** to print the first result for the standard(s) selected.

2nd Select **2nd** to print the second or duplicate result for the standard(s) selected.

Both Select **Both** to print first and duplicate calibration results.

Wavelength area

Primary, 2nd Use **Primary, 2nd** to print the absorbance data for the primary and secondary wavelengths.

(Primary) - (2nd) Use **(Primary)** - **(2nd)** to print only the bichromatic readings.

For an explanation of the **Reaction Monitor** report, see *Reaction Monitor report explanation* on page E-86.

Buttons

Print Choose this button to send the selected report to the printer and to store it in the print buffer.

Preview Choose **Preview** and then **View** to display a preview of the currently selected report without printing the report.

View Choose this button to view the lists and reports currently in the print buffer and also to write them to disk.

For more information, see:
Print View window on page E-70
Media Write window on page E-74

Calibrator Load List

➔ **Print** (global button) > **Calibration** > **Calibrator Load List**

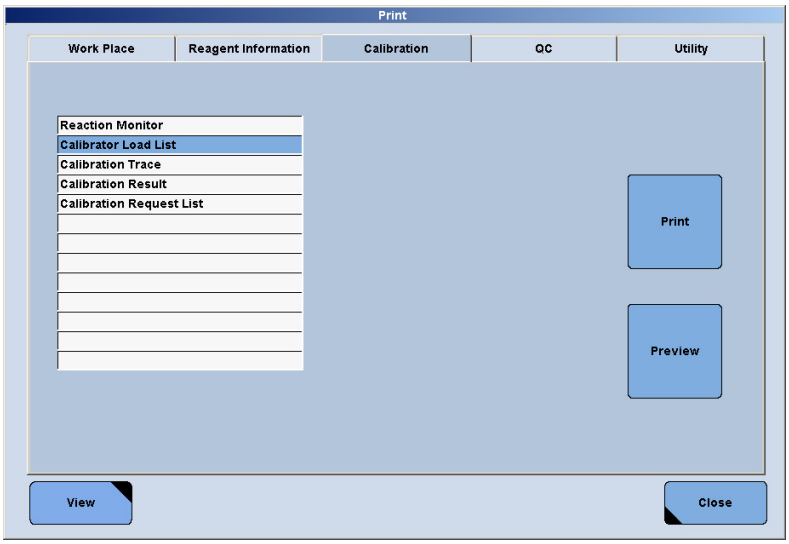


Figure E-64 Calibrator Load List print screen

Select **Calibrator Load List** from the report list to print a detailed list of the location for required standards.

For information on the tabs, see *Print screen* on page E-68.

Buttons

Print Choose this button to send the selected report to the printer and to store it in the print buffer.

Preview Choose **Preview** and then **View** to display a preview of the currently selected report without printing the report.

View Choose this button to view the lists and reports currently in the print buffer and also to write them to disk.

For more information, see:
Print View window on page E-70
Media Write window on page E-74

Calibration Load List report

```
                                Calibration Load List              07/10/08   09:24

NAME          LOT           R.NO.          EVENT     VOLUME
H2O           99999900                    ------   --------
CFAS          17715200                    ------   --------
ISELOW        69906400      S0002-1       ------   --------
ISEHIGH       69631400      S0002-2       ------   --------
ISECOMP       18191800      S0002-3       ------   --------
TSH-L1        182423                           2      196.0
TSH-L2        182423                           2      196.0
```

Figure E-65 Calibration Load List report

Calibration Load List report explanation

The **Calibration Load List** report gives a detailed description of where to place calibrators on the rack.

Date, Time The date and time the report was printed appears to the right of the report name.

NAME This column displays the name of each calibrator.

LOT This column displays the lot number of each calibrator.

R.NO. This column displays the assigned position of each standard on the calibrator rack.

EVENT This column displays the number of measuring channels that will be calibrated. This element is displayed only for **e** 601 tests.

VOLUME This column displays the calibrator volume that is needed for measurement (**e** 601 only). The dead volume of the individual sample cup is not considered. The total volume must be calculated by the operator.

➔ For information about the dead volume of the individual sample cups, see *Sample cups and tubes* on page A-116.

*Module-Specific Rack area (**e** 601)* This area provides details specific to the individual modules. (not displayed in Figure E-65)

MODULE This field displays the name of the module to which the rack is assigned.

RACK RANGE This field displays the rack range defined on **Utility** > **System** > **Change** (**Rack Assignment** area) > **Module Setting**.

➔ See *Module Setting tab* on page E-371.

EVENT This column displays the number of times a calibrator will be sampled.

VOLUME This column displays the calibrator volume that is needed for measurement. The dead volume of the individual sample cup is not considered. The total volume must be calculated by the operator.

Calibration Trace

➔ **Print** (global button) > **Calibration** > **Calibration Trace**

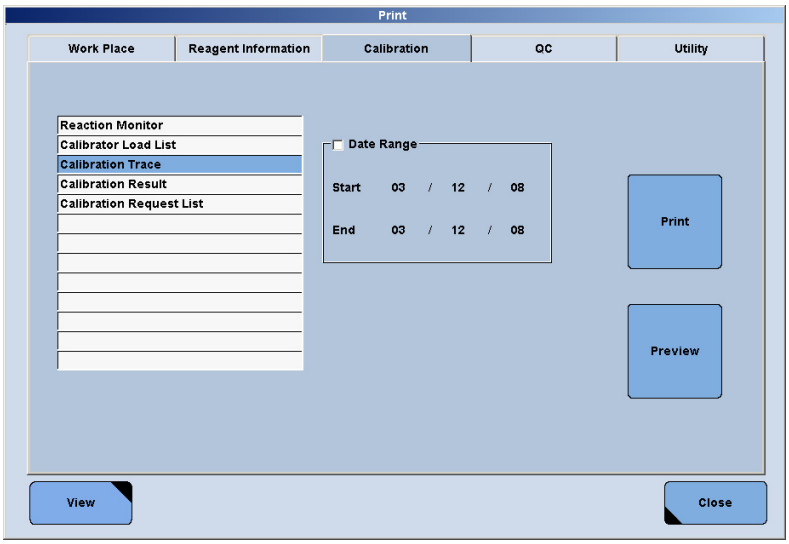


Figure E-66 Calibration Trace print screen

Prior to printing or viewing this report, select the desired data on **Calibration** > **Status**.

Select **Calibration Trace** from the report list to print the **Calibration Trace** report for all calibrators.

For information on the tabs, see *Print screen* on page E-68.

Date Range area

Date Range Select the **Date Range** check box to print the report for a range of dates. If selected, the **Start** and **End** date text boxes are activated. The date format (dd/mm/yy, mm/dd/yy, yy/dd/mm or yy/mm/dd) is defined in the **Date** list box on **Utility** > **System**.

See *Date and Time Setting area* on page E-362.

Start Type the first date of the date range to be printed on the report.

End Type the last date of the date range to be printed on the report.

Buttons

Print Choose this button to send the selected report to the printer and to store it in the print buffer.

Preview Choose **Preview** and then **View** to display a preview of the currently selected report without printing the report.

View Choose this button to view the lists and reports currently in the print buffer and also to write them to disk.

For more information, see:
Print View window on page E-70
Media Write window on page E-74

Calibration Trace report (c 501 (ISE))

```
                                        Calibration Trace                21/10/08 18:02

Cl-A                MODULE C
DATE      TIME      OP.ID   RESULT    CALIB LOT    RESULT  HIGH LOT  LOW LOT
                            --   (COMP. CONC.)   -- ------- (SLOPE)   --------

09/11     18:04     admin      767.7  17121900       -88.0  66724300  66724600
                              Cal.E                Rsp2.E
09/11     18:07     admin      145.7  17121900      -234.5  66724300  66724600
                              Cal.E                Rsp2.E
09/11     18:17     admin             17121900         0.6  66724300  66724600
                              Cal.E                Rsp2.E
09/11     18:20     admin      81.6   17121900       -55.7  66724300  66724600
                              Cal.E                 Cal.E
10/11     08:58     admin             17121900         3.4  66724300  66724600
                              Cal.E                Rsp2.E
10/11     09:02     admin             17121900         3.4  66724300  66724600
                              Cal.E                Rsp2.E
10/11     10:43     admin      97.1   17121900       -52.2  66724300  66724600
10/11     10:46     admin      97.5   17121900       -52.8  66724300  66724600
29/11     11:35     admin      97.8   17121900       -52.8  66724300  66724600
29/11     11:40     admin      97.3   17121900       -52.2  66724300  66724600
05/12     16:13     admin      97.4   17121900       -51.7  66724300  66724600
05/12     16:16     admin      97.8   17121900       -51.1  66724300  66724600
07/12     15:34     admin      96.9   17121900       -51.1  66724300  66724600
07/12     15:40     admin      97.0   17121900       -51.1  66724300  66724600
15/12     12:20     admin             17121900         0.0  66724300  66724600
                              Cal.E                Rsp2.E
15/12     12:23     admin      96.1   17121900       -50.5  66724300  66724600
15/12     13:18     admin      97.5   17121900       -51.7  66724300  66724600
15/12     13:21     admin      97.1   17121900       -50.5  66724300  66724600
15/12     16:09     admin      97.6   17121900       -51.1  66724300  66724600
15/12     16:12     admin      97.7   17121900       -49.4  66724300  66724600
02/01     12:10     admin      97.5   17121900       -53.4  66724300  66724600
02/01     12:13     admin      97.2   17121900       -52.8  66724300  66724600
02/01     14:59     admin      96.8   17121900       -52.8  66724300  66724600
02/01     15:02     admin      97.0   17121900       -52.8  66724300  66724600

COMMENTS
```

Figure E-67 Calibration Trace report (**c** 501 (ISE))

Calibration Trace report (c 501 (ISE)) explanation

Date, Time	The date and time the report was printed appears to the right of the report name.
Test	The short test name is printed in the upper left corner of the report.
MODULE	This field displays the name of the module and measuring channel in which the test is performed.
DATE	This column displays the date (as defined on the **Utility** >**System** screen) the calibration result was issued.
TIME	This column displays the time (hh:mm) the calibration result was issued.
OP. ID	This column displays the identification of the operator logged onto the system when the calibration was performed.
Result (COMP. CONC.)	This column displays the concentration value for ISE Std 3. The values are printed in mmol/L. An asterisk (*) next to the result shows that another calibration than Full calibration was performed.
CALIB LOT	This column displays the lot number of the ISE Std 3.
Result (SLOPE)	The Slope values displayed in this column are printed in millivolts/decade (mV).
Data Alarms	Data alarms are printed below the results.
HIGH LOT	This column displays the lot numbers of the ISE High standard.
LOW LOT	This column displays the lot numbers of the ISE Low standard.
COMMENTS	This area displays comments associated with the calibrations.

Calibration Trace report (c 501 module)

```
                                          Calibration Trace              21/10/08 18:02

TP2            MODULE C
DATE      TIME       OP.ID      RESULT   STD ID      RESULT   STD ID    RG_ID   SERIAL
                               -----(STD 1)-------  ----(STD 2-6)-----  ---CASSETTE ---

26/02     14:13      admin        -790   99999900       971   17467200  688394  13107
25/03     14:54      admin        -797   99999900       912   17881500  688394  13107
24/04     17:17      admin         875   99999900      -778   17715200  694376 *41350*
                               Sens.E              Sens.E
28/04     13:47      admin         848   99999900      -777   17715200  694376  41350
                               Sens.E              Sens.E
28/04     14:48      admin         879   99999900      -787   17715200  694376  41350
                               Sens.E              Sens.E
29/04     12:26      admin        -795   99999900       947   17715200  694376  41350
18/06     11:40      admin        -793   99999900       932   17882000  694376  41350
17/07     13:13      admin        -794   99999900       908   17882000  694376  41350
21/07     15:53      admin        -801   99999900       938   17882000  694376  41350
12/09     13:39      admin        -797   99999900       872   17882000  688394 *06968*
09/10     16:46      admin        -156   99999900      1106   18011800  688394  06971*

        COMMENTS
```

Figure E-68 Calibration Trace report (**c** 501 (P))

Calibration Trace report (c 501 module) explanation

Date, Time The date and time the report was printed appears to the right of the report name.

Test The short test name is printed in the upper left corner of the report.

MODULE This field displays the name of the module and measuring channel in which the test is performed.

DATE This column displays the date (as defined on the **Utility** >**System** screen) the calibration result was issued.

TIME This column displays the time (hh:mm) the calibration result was issued.

OP. ID This column displays the identification of the operator logged onto the system when the calibration was performed.

RESULT Absorbance values for Std 1 and Std 2 to 6 are listed here. The absorbance of the highest standard is printed for nonlinear tests. An asterisk (*) next to the result shows that another calibration method than the recommended method was performed. For example, an asterisk is shown, if a full calibration is recommended and a 2 Point calibration is performed.

In case of a rate assay, it indicates the primary wavelength absorbance at photometric measuring point 1 of Std (1).

Data Alarms Data alarms are printed below the results.

STD ID This column displays the lot number of the respective standard (Std 1 or Std 2 to 6).

RG_ID (CASSETTE) This column lists the reagent lot numbers on the **c** 501 (P). An asterisk (*) indicates a lot changeover.

SERIAL (CASSETTE) This column lists the sequence numbers of the calibrated **cobas c** packs. An asterisk (*) indicates a cassette changeover.

COMMENTS This area displays comments associated with the calibrations.

Calibration Trace report (e 601 module)

```
                              Calibration Trace                        14/11/08     16:20

AFP           MODULE E1-1
DATE TIME     OP. ID     CALIBRATOR LOT      SIGNAL     SIGNAL      LOT        SERIAL
                         --------------      -(Min)--   -(Max)--    -----------------

24/10 09:58   admin      00159661              16296     118355    00159662   002911
24/10 10:50   admin      00159661             118352      16302 *  00159662   002911

COMMENTS
```

Figure E-69 Calibration Trace report (**e** 601)

Calibration Trace report (e 601 module) explanation

The **Calibration Trace** report displays a maximum of the last 50 calibrations.

Date, Time The date and time the report was printed appears to the right of the report name.

Test The short test name is printed in the upper left corner of the report.

MODULE This field displays the name of the module and measuring channel for which the print out was selected.

DATE This column displays the date when the calibration result was issued.

TIME This column displays the time when the calibration result was issued.

OP. ID This column displays the identification of the operator logged onto the system when the calibration was performed.

CALIBRATOR LOT This column displays the lot number of the calibrator. An asterisk (*) is displayed to the right of this column if the lot number is different from the previous one.

SIGNAL (Min) This column displays the mean of the measured values for the calibrator level 1. An asterisk (*) is displayed to the right of this column if a calibration criterion is not fulfilled. If no signal was detected by the measuring cell the printout displays '----'.

SIGNAL (Max) This column displays the mean of the measured values for the calibrator level 2. An asterisk (*) is displayed to the right of this column if a calibration criterion is not fulfilled. If no signal was detected by the measuring cell the printout displays '----'.



If a calibration is failed because of the *factor*, the calibration trace will not indicate a failed calibration (no asterisk (*) is displayed).

LOT This column displays the lot number of the **cobas e** pack that was used for the calibration. An asterisk (*) is displayed to the right of this column if the lot number is different from the previous one.

SERIAL This column displays the **cobas e** pack number that was used for the calibration. An asterisk (*) is displayed to the right of this column if the serial number is different from the previous one.

COMMENTS This area displays comments associated with the calibrations.

Calibration Result

➔ **Print** (global button) > **Calibration** > **Calibration Result**

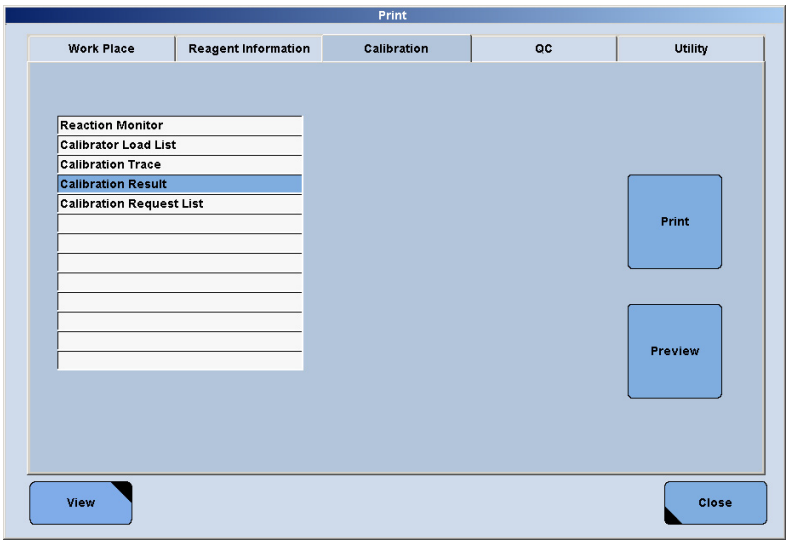


Figure E-70 Calibration Result print screen

Select **Calibration Result** from the report list to print a detailed list of calibration results for photometric tests. No criteria need to be selected in order to print this report.

For information on the tabs, see *Print screen* on page E-68.

Buttons

Print Choose this button to send the selected report to the printer and to store it in the print buffer.

Preview Choose **Preview** and then **View** to display a preview of the currently selected report without printing the report.

View Choose this button to view the lists and reports currently in the print buffer and also to write them to disk.

For more information, see:
Print View window on page E-70
Media Write window on page E-74

Calibration Result report

```
                          Calibration Result List                 21/10/08      18:02

MODULE C
TEST      S1Abs.  --- K ---  --- A ---  --- B ---  --- C ---  -- L -    -- H -    -- I -
ALBS2        239  1.368E+2   1.023E+0   2.871E+4
ALBU2        236  5.865E+2   1.014E+0   2.936E+4
AMY-P          0     30920
ASTLP         -7    -27101
CA           839       885
CHO2I       1455      1033
CKMBL         10     27505
GGTI2          2      6541
GLUC2        194      1635
IRON2        103    295598
SCRE2         -1      9435
SI2           10     99999                                  -1         1         0
TP2         -797      3158
TP2         -801      3030
TRIGL        744       835
UA2           33      2597
```

Figure E-71 Calibration Result report

Calibration Result report explanation

The **Calibration Result** report displays the results of the most recent calibrations measured on the **c** 501 module.

Date, Time The date and time the report was printed appears to the right of the report name.

MODULE This field displays the name of the module for which the calibration has been measured.

TEST This column displays the short test name for the application.

S1Abs. This column displays the absorbance of standard (1).

K This column displays the reciprocal value of the slope of the calibration curve (K factor).

A This column displays the nonlinear coefficient A (slope).

B This column displays the nonlinear coefficient B (intercept).

C This column displays the nonlinear coefficient C (cubic spline exponential).

L This column displays the bichromatic absorbance difference of the lipemia serum index.

H This column displays the bichromatic absorbance difference of the hemolysis index.

I This column displays the bichromatic absorbance difference of the icterus index.

Calibration Request List

➔ **Print** (global button) > **Calibration** > **Calibration Request List**

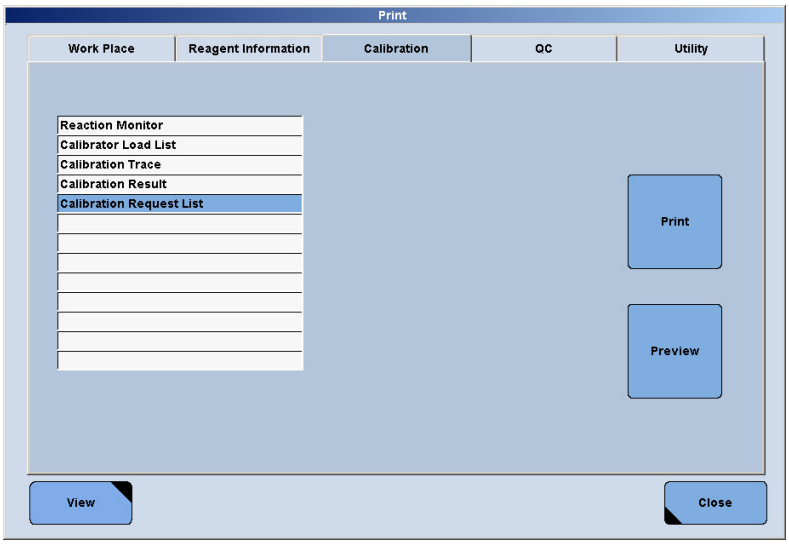


Figure E-72 Calibration Request List print screen

Select **Calibration Request List** from the report list to print a detailed list of reagents selected for calibration. No criteria need to be selected in order to print this report.

For information on the tabs, see *Print screen* on page E-68.

Buttons

Print Choose this button to send the selected report to the printer and to store it in the print buffer.

Preview Choose **Preview** and then **View** to display a preview of the currently selected report without printing the report.

View Choose this button to view the lists and reports currently in the print buffer and also to write them to disk.

For more information, see:
Print View window on page E-70
Media Write window on page E-74

Calibration Request List report

```
                                    Calibration Request List       21/10/08  18:02

MODULE C
TEST          LOT           SERIAL        ORDER
GGTI2         698959        8042          2POINT
GLUC2         603037        1699          2POINT
IGG-2         602803        313           FULL
IRON2         601204        5529          2POINT
SCRE2         692145        17928         2POINT
TRIGL         698219        5283          2POINT
ISE-A-IS1                                 FULL
ISE-A-IS2                                 FULL
ISE-B-IS1                                 FULL
ISE-B-IS2                                 FULL

MODULE E1
TEST          LOT           SERIAL        ORDER
CK-MB         00181768      44616         ch1 ch2
HCG-BETA      00181827      47964         ch1 ch2
TSH           00152136      6177          ch1 ch2
TSH           00150163      22907         ch1
```

Figure E-73 Calibration Request List report

Calibration Request List report explanation

The **Calibration Request List** gives a description of which calibrations have been requested.

Date, Time The date and time the report was printed appears to the right of the report name.

MODULE This field displays the name of the module for which the calibration has been requested.

TEST This column displays the short test name for the application.

LOT This column displays the lot number of the **cobas c** pack or **cobas e** pack for which the calibration has been requested.

SERIAL This column displays the sequence number of the **cobas c** pack or **cobas e** pack for which the calibration has been requested.

ORDER This column displays for which channel the calibration was requested.

For photometric and ISE calibrations the different calibration methods are displayed.

Calibration Monitor report

This report is printed automatically by the system, if selected for automatic printout. To toggle the automatic generation, select **Utility** > **System** (**Page 4/4**) > **Automatic Printout** and select or clear the **Calibration Monitor** check box.

See *Automatic Printout Setting window* on page E-418.

The **Calibration Monitor** report displays calibration information for the calibrations that were currently performed. The calibration report differs depending on the module that was calibrated (**c** 501 (ISE) or (P) or **e** 601).

For individual report examples and explanations, see:
ISE Calibration Monitor report on page E-121
ISE Calibration Monitor report explanation on page E-122
Photometric Calibration Monitor report on page E-123
Photometric Calibration Monitor report explanation on page E-123
Immunology Calibration Monitor report on page E-125
Immunology Calibration Monitor report explanation on page E-126

ISE Calibration Monitor report

```
                          Calibration Monitor                  13/10/08      14:07

13/10/08  14:07:29   admin    C1
TEST         IS.EMF    S1 EMF     S2 EMF    S3 EMF     SLOPE  IS.CONC.    S3 CONC.   C.VALUE
Na-A-IS1      -40.0     -44.5      -37.1     -39.8      59.2       143         144        -2

K-A-IS1       -49.6     -62.7      -40.6     -51.9      60.1      4.95        4.54     -0.08

Cl-A-IS1      137.6     141.9      133.7     136.8     -46.2      96.0         102        -1


13/10/08  14:07:29   admin    C1
TEST         IS.EMF    S1 EMF     S2 EMF    S3 EMF     SLOPE  IS.CONC.    S3 CONC.   C.VALUE
Na-B-IS1      -40.0     -44.5      -37.1     -39.8      59.2       143         144        -2

K-B-IS1       -49.6     -62.7      -40.6     -51.9      60.1      4.95        4.54     -0.08

Cl-B-IS1      137.6     141.9      133.7     136.8     -46.2      96.0         102        -1
```

Figure E-74 Calibration Monitor report **c** 501 (ISE)

ISE Calibration Monitor report explanation

Date, Time, Operator ID The date and time the report was printed appears to the right of the report name.

The date, time and operator ID at the time the calibration result was issued are located on the left immediately preceding the corresponding calibration information.

Module The module on which the calibration was performed is shown to the right of the operator ID.

TEST This column lists the name of each ISE test (Na, K, Cl), the type of calibration curve that was used (A or B) and the internal standard bottle that was used (IS1 or IS2), for example Na-B-IS1.

IS. EMF This column lists the electromotive force (EMF) or electrical potential generated by the internal standard solution at the specified electrolyte cartridge. The value is printed in millivolts (mV).

S1 EMF This column lists the electrical potential (mV) generated by the ISE Low standard for the specified electrolyte cartridge.

S2 EMF This column lists the electrical potential (mV) generated by the ISE High standard for the specified electrolyte cartridge.

S3 EMF This column lists the electrical potential (mV) generated by the ISE Std 3 calibrator for the specified electrolyte cartridge.

SLOPE This column lists the sensitivity of the specified electrolyte cartridge. The slope should gradually decrease with time, reflecting the aging of the cartridge.

When the slope falls outside of the optimal slope range values, a warning data alarm and an instrument alarm are issued.

For information about calibration quality criteria, refer to the COBI CD.

IS. CONC. This column lists the measured concentration (mmol/L) of the internal reference solution determined during calibration.

S3 CONC. This column lists the measured concentration (mmol/L) of the serum based calibrator determined during calibration.

C. VALUE This column lists the compensation value (mmol/L) determined during calibration. This value is the difference between the measured concentration of STD 3 shown in the S3 Conc. column and the actual value of STD 3 (as entered on the **Calibration** > **Install** screen). This value is added to or subtracted from all subsequent control and patient values.

Calibration alarms If a calibration alarm occurs, it is printed below the corresponding result.

Photometric Calibration Monitor report

```
                                Calibration Monitor                13/10/08  14:16

      13/10/08  admin       C2
      14:16:23  99999900          17715200
          TRIGL ------S1-----    -----S2----
                  636     639   2995     3057   S1ABS   K           LOT    SERIAL
                  636     642   2995     3055     636     742     604815  35694


      13/10/08  admin       C2
      14:16:35  99999900              17715200
          GLUC2  -----S1-----     -----S2----
                  140    1109   7332     8742   S1ABS   K           LOT    SERIAL
                  145    1113   7399     8816     143   1509      603037  16166
```

Figure E-75 Photometric Calibration Monitor report

Photometric Calibration Monitor report explanation

Date, Time, Operator ID The date and time this report was printed are shown in the upper right of the report.

The date, time and operator ID at the time the calibration result was issued are located on the left immediately preceding the corresponding calibration information.

Module The module on which the calibration was performed is shown to the right of the operator ID.

LOT Nos. Standards 1 through 6 The lot numbers of standards 1 through 6 are shown to the right of the calibration time.

Test The short test name is printed below the calibration time. Any data alarm that affects an entire test is printed two rows below the test name. Some alarms include: Std.E, SD.E …

For information about calibration quality criteria, refer to the COBI CD.

S1 through S6 Absorbance measurements for standards 1 through 6 are printed in separate columns across the page.

- Replicate absorbance measurements are printed, one below the other, under the standard levels.
- For each standard level there are two columns. The first column corresponds to the measurement of the primary-secondary wavelength and the second column corresponds to the measurement of the primary wavelength.
- If calibration alarms are present, the alarm is printed below the affected standard.

For information about calibration quality criteria, refer to the COBI CD.

Calibration Curve Parameters

The calibration curve parameters (such as S1ABS, K, A, B) are printed in separate columns next to or beneath the absorbance measurements.

Some calibration or data alarms do not generate values that allow calculating the curve parameters (Samp.S, Sens.E, Dup.E …). If one of these alarms is present, no curve parameters are generated. If an application which requires a multi point *Full* calibration is not calibrated with all calibrators, the calibration curve will generate Factor 1 and Factor 2 values to update the curve.

For information about calibration quality criteria, refer to the COBI CD.

LOT

The lot number of the appropriate **cobas c** pack is shown in the column to the right of the calibration curve parameters.

SERIAL

The serial number of the appropriate **cobas c** pack is shown in the column to the right of the lot number.

Immunology Calibration Monitor report

```
                          Calibration Monitor          13/10/08                14:21

13/10/08       admin          E1-1
14:21:15       L-Calib. could not be generated!            Released as R-Calib. by System
               Calib.with expired RackPack

TEST           UNIT           CALIBRATOR LOT       LOT       SERIAL
---------------------         --------------       ---------------------
TSH            uIU/mL          00182423            00181176  104187

               -----S1-----       -----S2-----
TARGET            0.000                 1.88
SIGNAL1            1314                32315
SIGNAL2            1289                32007
Monotony             --                   --
Diff.                --                   --
Dupl.                --                   --
SysErr               --                   --
FACTOR             1.00


13/10/08       admin          E1-2
14:21:36       L-Calib. could not be generated!            Released as R-Calib. by System
               Calib.with expired RackPack

TEST           UNIT           CALIBRATOR LOT       LOT       SERIAL
---------------------         --------------       ---------------------
TSH            uIU/mL          00182423            00181176  104187
               -----S1-----            -----S2-----
TARGET            0.000                 1.88
SIGNAL1            1310                31234
SIGNAL2            1254                31170
Monotony             --                   --
Diff.                --                   --
Dupl.                --                   --
SysErr               --                   --
FACTOR             1.00
```

Figure E-76 Immunology Calibration Monitor report

Immunology Calibration Monitor report explanation

The **Calibration Monitor** report is divided into three sections, the header and the two detail sections (tables).

- The header displays general information about the calibration.
 See *Header*.
- The first detail section displays general information about the calibrator.
 See *General information about the calibrator*.
- The second detail section displays information about the calibration quality criteria.
 See *Results and calibration quality criteria*.

Header

```
                          Calibration Monitor            13/10/08                  14:21

13/10/08       admin          E1-1
14:21:15       L-Calib. could not be generated!             Released as R-Calib. by System
               Calib.with expired RackPack

TEST           UNIT           CALIBRATOR LOT       LOT       SERIAL
...
```

Figure E-77 Immunology Calibration Monitor report - header

The header contains the date and time when the calibration result was issued, the operator ID, the name of the module and measuring channel on which the calibration was measured, and comments about the calibration.

General information about the calibrator

The first detail section (table) displays information about the **cobas e** pack and the calibrator.

```
...
TEST           UNIT           CALIBRATOR LOT       LOT       SERIAL
----------------------        --------------       ----------------------
TSH            uIU/mL          00182423           00181176  104187

               -----S1-----        -----S2-----
TARGET           0.000                 1.88
SIGNAL1           1314                32315
...
```

Figure E-78 Immunology Calibration Monitor report - **cobas e** pack and calibrator information

TEST This column displays the report test name.

UNIT This column displays the unit of measure for each test as defined on the **Utility** > **Application** screen.

CALIBRATOR LOT This column displays the lot number of the calibrator used.

LOT This column displays the lot number of the **cobas e** pack used for the calibration.

SERIAL This column displays the serial number of the **cobas e** pack used for the calibration.

Results and calibration quality criteria

The second detail section (table) displays the calibration results and the calibration quality criteria.

For more information about calibration quality criteria, see *Calibration quality criteria for immunological applications* on page B-164 and refer to the *COBI-CD*.

This section displays different information for quantitative and qualitative tests. The following report shows an example for a quantitative test.

```
...
TEST           UNIT           CALIBRATOR LOT       LOT       SERIAL
---------------------         --------------       ---------------------
TSH            uIU/mL          00182423            00181176  104187

                -----S1-----        -----S2-----
TARGET            0.000                 1.88
SIGNAL1            1314                 1318 <Sig
SIGNAL2              NG                32007
Monotony             --                   --
Diff.                --                   --
Dupl.                --                   --
SysErr               --                   --
FACTOR             1.00
...
```

Figure E-79 Immunology Calibration Monitor report for quantitative assays - calibration quality criteria

Columns S1/S2 The columns S1 and S2 display the information for calibrator level 1 and calibrator level 2.

TARGET The target value of the calibrator level 1 and 2.

SIGNAL1, SIGNAL2 The result of the first and the second measurement of calibrator level 1 and 2.

- **<Sig**: The calibrator signal is lower than the specified lower limit value.
- **>Sig**: The calibrator signal is higher than the specified upper limit value.
- **NG**: No calibrator signal was detected by the measuring cell.

For **Monotony**, **Diff.**, **Dupl.**, and **SysErr** the following flags are displayed:

- If the criterion is met, -- is displayed.
- If the criterion is not met, **NG** is displayed.

Monotony All measured calibrator values must fall in ascending or descending order.

Diff. The minimum difference of the values between calibrator level 1 and 2 must be 30%.

Dupl. Deviation of duplicate measurement must be below 10% for most of the assays.

SysErr A hardware error occurred during the measurement.

FACTOR The factor of a lot calibration (L-Calib.) is 1.00. The factor of a reagent pack calibration (R-Calib.) must lie between 0.8-1.2. Otherwise, a calibration could not be released and a message is displayed in the header of the report.

The following report shows an example for a qualitative test.

```
...
TEST          UNIT          CALIBRATOR LOT       LOT       SERIAL
--------------------        --------------       ----------------------
HBSAGII       COI            00182273            00182273  007435

               -----S1-----       -----S2-----
SIGNAL1            1409                  4262
SIGNAL2            1434                  4265
Dupl.                --                    --
SysErr               --                    --
Slope                --                    --
Diff.                --                    --
CutOff             417.5
Border area        0.900        -        1.00
...
```

Figure E-80 Immunology Calibration Monitor report for qualitative assays - calibration quality criteria

Columns S1/S2 The columns S1 and S2 display the information for calibrator level 1 and calibrator level 2.

Signal1, Signal2 The result of the first and the second measurement.

- **<Sig**: The calibrator signal is lower than the specified lower limit value.
- **>Sig**: The calibrator signal is higher than the specified upper limit value.
- **NG**: No calibrator signal was measured.

For **Dupl.**, **SysErr**, **Slope**, and **Diff.** the following flags are displayed:

- If the criterion is met, -- is displayed.
- If the criterion is not met, **NG** is displayed.

Dupl. Deviation of duplicate measurement must be below 10% for most of the assays.

SysErr A hardware error occurred during the measurement.

Slope All measured calibrator values must fall in ascending or descending order (Monotony of curve).

Diff. The minimum difference of the values between calibrator level 1 and 2 must be 30%.

CutOff Cutoff value of the calibration.

For more details, refer to the instructions for use of the test.

Border area The upper and lower limit of the area.

For more details, refer to the instructions for use of the test.

QC print screen

➔ **Print** (global button) > **QC**

The **QC** print screen displays a list of reports relating to the **QC** menu. The screen changes depending on the report selected.

Individual QC Chart

➔ **Print** (global button) > **QC** > **Individual QC Chart**

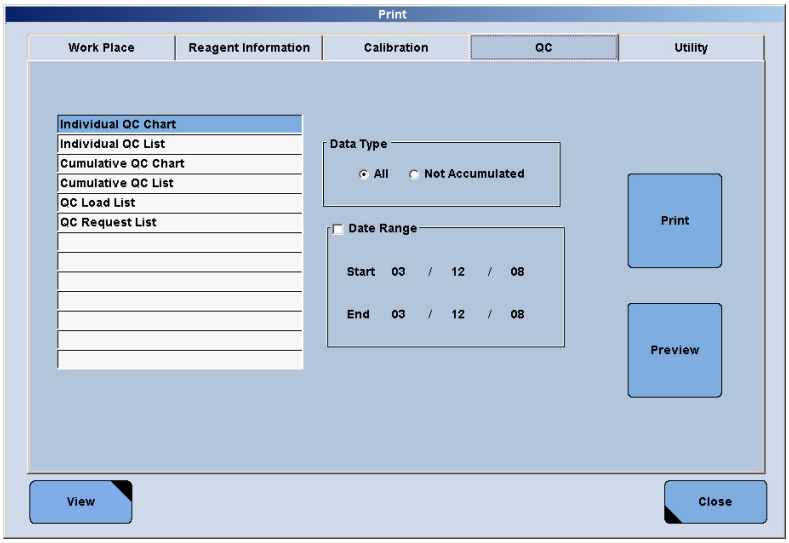


Figure E-81 Individual QC Chart print screen

Prior to printing or viewing this report, select the desired data on **QC** > **Individual**.

Select **Individual QC Chart** from the report list to print the **Individual QC Chart** report for the selected data.

For information on the tabs, see *Print screen* on page E-68.

Data Type area

All Select **All** to print all QC results in chart format.

Not Accumulated Select **Not Accumulated** to print only unaccumulated QC results in chart format.

Date Range area

Date Range Select the **Date Range** check box to print the report for a range of dates. If selected, the **Start** and **End** date text boxes are activated. The date format (dd/mm/yy, mm/dd/yy, yy/dd/mm or yy/mm/dd) is defined in the **Date** list box on **Utility** > **System**.

See *Date and Time Setting area* on page E-362.

Start Type the first date of the date range to be printed on the report.

End Type the last date of the date range to be printed on the report.

Buttons

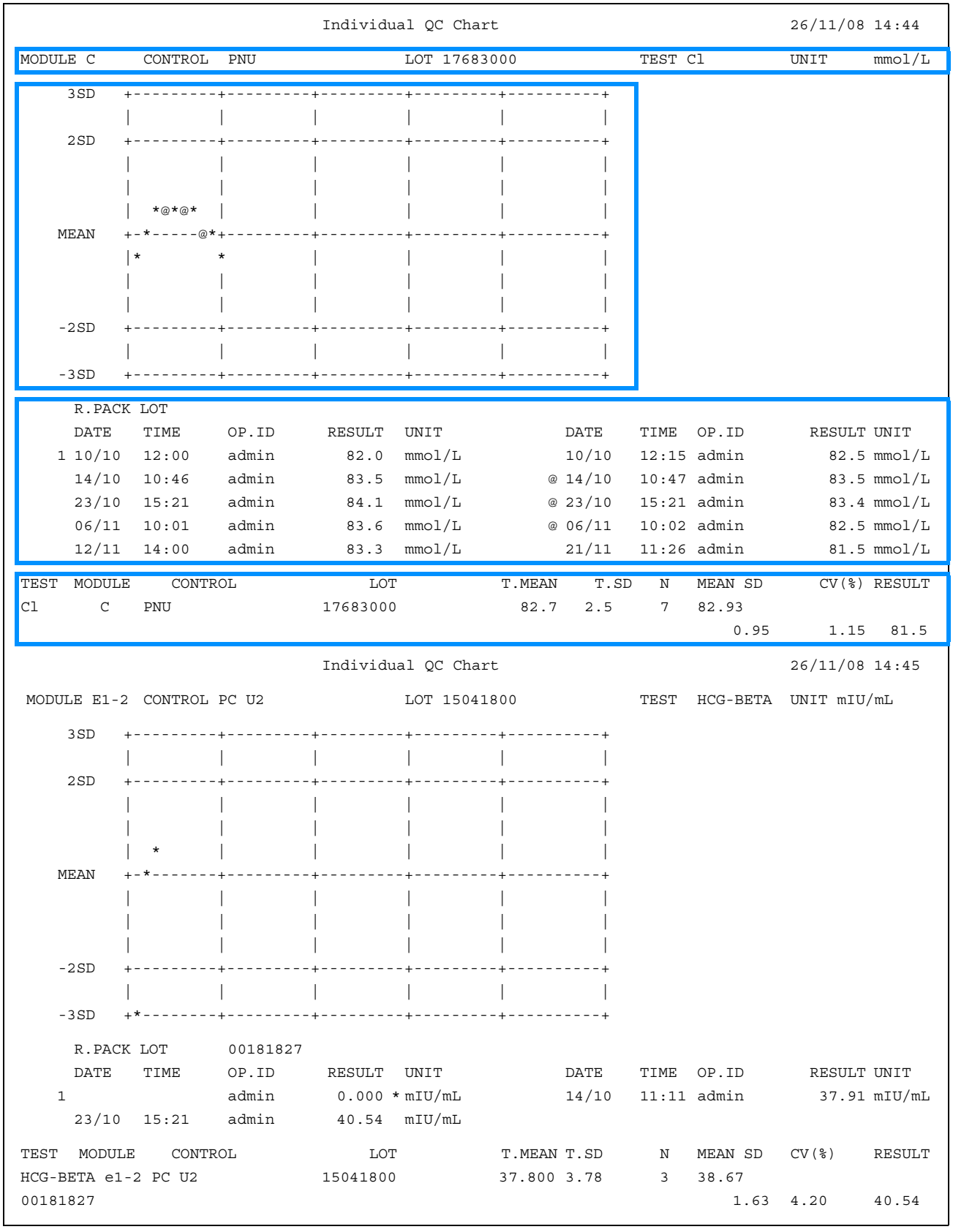
Print Choose this button to send the selected report to the printer and to store it in the print buffer.

Preview Choose **Preview** and then **View** to display a preview of the currently selected report without printing the report.

View Choose this button to view the lists and reports currently in the print buffer and also to write them to disk.

For more information, see:
Print View window on page E-70
Media Write window on page E-74

Individual QC Chart report



```
                                Individual QC Chart                                26/11/08 14:44

MODULE C      CONTROL  PNU                LOT 17683000             TEST Cl          UNIT      mmol/L

     3SD   +---------+---------+---------+---------+----------+
           |         |         |         |         |          |
     2SD   +---------+---------+---------+---------+----------+
           |         |         |         |         |          |
           |         |         |         |         |          |
           |  *@*@*  |         |         |         |          |
    MEAN   +-*-----@*+---------+---------+---------+----------+
           |*        *         |         |         |          |
           |         |         |         |         |          |
           |         |         |         |         |          |
    -2SD   +---------+---------+---------+---------+----------+
           |         |         |         |         |          |
    -3SD   +---------+---------+---------+---------+----------+

      R.PACK LOT
      DATE    TIME      OP.ID      RESULT   UNIT              DATE    TIME   OP.ID        RESULT UNIT
    1 10/10   12:00     admin        82.0   mmol/L             10/10   12:15  admin          82.5 mmol/L
      14/10   10:46     admin        83.5   mmol/L           @ 14/10   10:47  admin          83.5 mmol/L
      23/10   15:21     admin        84.1   mmol/L           @ 23/10   15:21  admin          83.4 mmol/L
      06/11   10:01     admin        83.6   mmol/L           @ 06/11   10:02  admin          82.5 mmol/L
      12/11   14:00     admin        83.3   mmol/L             21/11   11:26  admin          81.5 mmol/L

TEST  MODULE     CONTROL              LOT           T.MEAN    T.SD    N    MEAN SD       CV(%) RESULT
Cl       C     PNU                17683000             82.7    2.5     7    82.93
                                                                                 0.95        1.15   81.5

                                Individual QC Chart                                26/11/08 14:45

 MODULE E1-2  CONTROL PC U2              LOT 15041800             TEST   HCG-BETA  UNIT mIU/mL

     3SD   +---------+---------+---------+---------+----------+
           |         |         |         |         |          |
     2SD   +---------+---------+---------+---------+----------+
           |         |         |         |         |          |
           |         |         |         |         |          |
           |  *      |         |         |         |          |
    MEAN   +-*-------+---------+---------+---------+----------+
           |         |         |         |         |          |
           |         |         |         |         |          |
           |         |         |         |         |          |
    -2SD   +---------+---------+---------+---------+----------+
           |         |         |         |         |          |
    -3SD   +*--------+---------+---------+---------+----------+

      R.PACK LOT       00181827
      DATE    TIME      OP.ID      RESULT   UNIT              DATE    TIME   OP.ID        RESULT UNIT
    1                   admin       0.000 * mIU/mL             14/10   11:11  admin         37.91 mIU/mL
      23/10   15:21     admin       40.54   mIU/mL

TEST   MODULE     CONTROL              LOT           T.MEAN T.SD      N    MEAN SD   CV(%)     RESULT
HCG-BETA e1-2 PC U2              15041800           37.800 3.78      3    38.67
00181827                                                                    1.63   4.20      40.54
```

Figure E-82 Individual QC Chart report

Individual QC Chart report explanation

The first line of the report displays the report name and the date and time the report was printed.

The actual **Individual QC Chart** report is divided into four sections:

- Header
 See *Header*.
- QC chart
 See *Chart*.
- Results section
 See *Results*.
- Statistics section
 See *Statistics*.

Header

MODULE This field displays the name of the module and measuring channel for which the QC statistic is displayed.

CONTROL This field displays the name of the selected control.

LOT This field displays the lot number of the selected control.

TEST This field displays the short test name of the selected test.

UNIT This field displays the unit of measure for the selected control.

Chart

The values (in SD) of the controls measured are plotted on the Y-axis and time on the X-axis. All points should lie within the ±3SD range. If a point falls outside of this range, corrective action is required.

Each point on the chart represents one individual control result for a test.

- An exclamation mark (!) indicates a reagent lot change.
- An at sign (@) indicates the results have been excluded.

Results

The results section (table) displays information about the QC results displayed in the chart.

...

	R.PACK LOT										
	DATE	TIME	OP.ID	RESULT	UNIT		DATE	TIME	OP.ID	RESULT	UNIT
1	10/10	12:00	admin	82.0	mmol/L		10/10	12:15	admin	82.5	mmol/L
	14/10	10:46	admin	83.5	mmol/L	@	14/10	10:47	admin	83.5	mmol/L
	23/10	15:21	admin	84.1	mmol/L	@	23/10	15:21	admin	83.4	mmol/L
	06/11	10:01	admin	83.6	mmol/L	@	06/11	10:02	admin	82.5	mmol/L
	12/11	14:00	admin	83.3	mmol/L		21/11	11:26	admin	81.5	mmol/L

...

Figure E-83 Individual QC Chart report - results

R.PACK LOT This field displays the lot number of the **cobas e** pack used for the QC measurement. For each lot a separate result and statistics section is displayed.

For **cobas c** packs no lot number is displayed.

DATE This column displays the date of each control run. An asterisk (*) before the date indicates the results have been accumulated and an at sign (@) indicates the results have been excluded. The number 1, 11, 21 etc. in front of the date indicates the order of these control results.

TIME This column displays the time when each control was registered by the barcode reader.

OP. ID This column displays the identification of the operator logged onto the system when the control was run.

RESULT This column displays each measurement result followed by any data alarm that has been issued.

If the result is not in the range MEAN ±2 SD, an asterisk (*) is printed to the right of the data alarm. If a Cal.E alarm occurred, it is printed below the result.

Statistics

The statistics section (table) displays statistical data about the QC results displayed in the chart.

```
...

TEST  MODULE     CONTROL              LOT            T.MEAN    T.SD    N    MEAN SD      CV(%) RESULT
Cl       C    PNU                 17683000             82.7    2.5     7    82.93
                                                                                 0.95      1.15   81.5

...
```

Figure E-84 Individual QC Chart report - statistics

TEST This column displays the short test name of the selected test.

MODULE This column displays the name of the module and measuring channel for which the QC statistic is displayed.

CONTROL This column displays the name of the selected control.

LOT This column displays the lot number of the selected control.

T.MEAN This column displays the target mean for the selected test and control level, as specified on **QC** > **Install**.

The target mean may be different for different **cobas e** pack lots, even if the same control lot is used. Thus, for each **cobas e** pack lot a separate result and statistics section is displayed.

T.SD This column displays the target standard deviation for the selected test and control level, as specified on **QC** > **Install**.

N This column displays the number of control results which are evaluated in the statistic.

MEAN This column displays the calculated mean for the set (N) of individual control values.

SD This column displays the calculated standard deviation for the set (N) of individual control values.

CV(%) This column displays the calculated coefficient of variation (CV) for the set (N) of individual control values.

RESULT This column displays the most recent result of this control.

All statistics are calculated based on all available QC results, irrespective of the selected date range. Accumulated and excluded results are not considered for the calculation.

Individual QC List

➔ **Print** (global button) > **QC** > **Individual QC List**

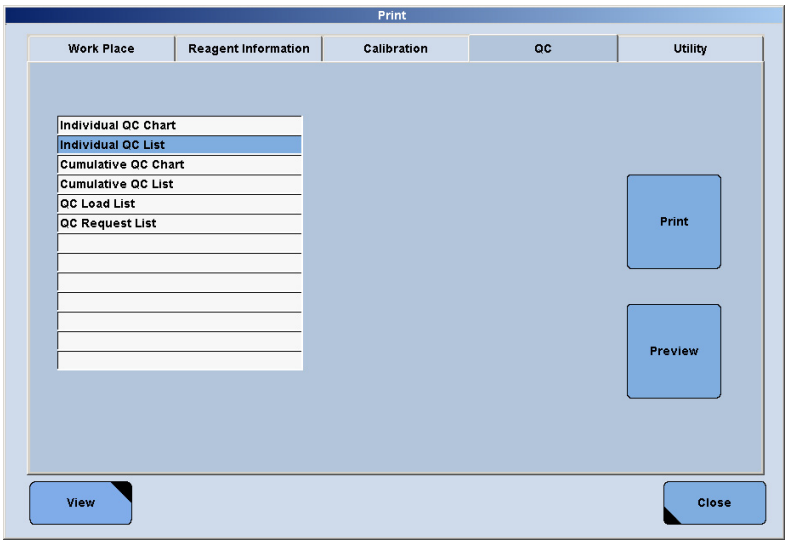


Figure E-85 Individual QC List print screen

Prior to printing or viewing this report, select the desired data on **QC** > **Individual**.

Select **Individual QC List** from the report list to print the **Individual QC List** for the selected results.

For information on the tabs, see *Print screen* on page E-68.

Buttons

Print Choose this button to send the selected report to the printer and to store it in the print buffer.

Preview Choose **Preview** and then **View** to display a preview of the currently selected report without printing the report.

View Choose this button to view the lists and reports currently in the print buffer and also to write them to disk.

For more information, see:
Print View window on page E-70
Media Write window on page E-74

Individual QC List report

```
                                Individual QC List                    26/11/08   14:56

TEST      MODULE        CONTROL          LOT  T.MEAN   T.SD    N   MEAN SD     CV(%)  RESULT
CHO2I       C       PNU             17683000      2.50   0.13   1   2.410
                                                                                      2.41
CHO2I       C       PPU             17628700      5.30   0.26   1   5.180
                                                                                      5.18
CK-MB       e1-1    PC  CARD1       18009500     5.150 0.515   2    2.43
00181768                                                          0.197    8.10     2.29
CK-MB       e1-1    PC  CARD2       18009600     58.50  5.85   2   45.92
00181768                                                          0.201            46.07
CK-MB       e1-2    PC  CARD1       18009500     5.150 0.515   2    2.44
00181768                                                          0.018    0.74     2.42
CK-MB       e1-2    PC  CARD2       18009600     58.50  5.85   2   45.97
00181768                                                          0.477    1.04    45.63
Cl          C       PNU             17683000      82.7   2.5   7   82.93
                                                                   0.95    1.15     81.5
Cl          C       PPU             17628700       112     3   7  112.96
                                                                   1.63    1.44    112.0
```

Figure E-86 Individual QC List report

Individual QC List report explanation

If some or all tests are configured for QC Violation (QC-triggered calibration recommendations), the **Individual QC List** is divided into 2 sections:

- QC Violated Tests: Displays all QC measurements that exceed the test-specific confidence limits.
- Other Tests: Displays all other QC measurements.

Date, Time The date and time the report was printed appears to the right of the report name.

TEST This column displays the short test name of the selected test of the **cobas c** pack or **cobas e** pack used for the control measurement. The lot number of the **cobas e** pack is displayed below the short test name.

MODULE This column displays the name of the module and measuring channel in which QC was performed.

CONTROL This column displays the name of the selected control, as specified on **QC** > **Install**.

LOT This column displays the lot number of the selected control, as specified on **QC** > **Install**.

T.MEAN This column displays the target mean for the selected test and control level.

T.SD This column displays the target standard deviation for the selected test and control level.

N This column displays the number of times the control is evaluated in this statistic for each test.

MEAN This column displays the calculated mean for the set of individual control values for each test.

SD This column displays the calculated standard deviation for the set of individual control values for each test.

CV(%) This column displays the calculated coefficient of variation (CV) for the set of individual control values for each test.

RESULT This column displays the most recent result.

Cumulative QC Chart

➔ **Print** (global button) > **QC** > **Cumulative QC Chart**

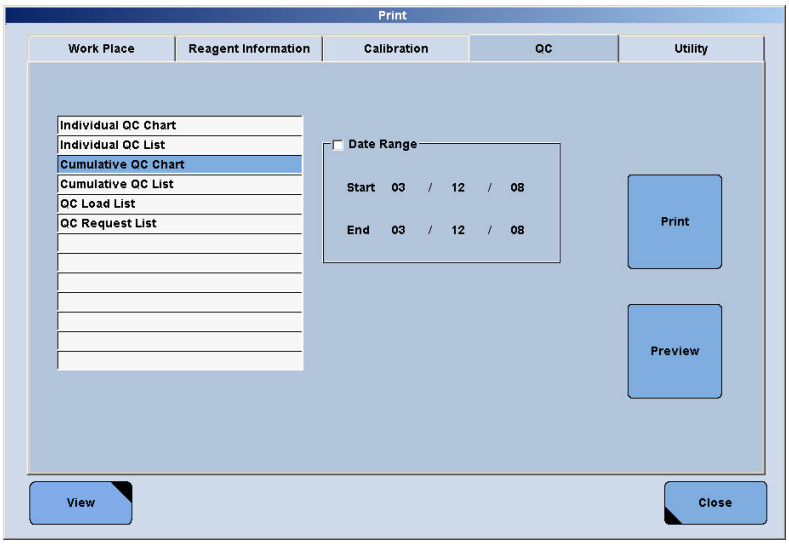


Figure E-87 Cumulative QC Chart print screen

Prior to printing or viewing this report, select the desired data on **QC** > **Cumulative**.

Select **Cumulative QC Chart** from the report list to print the **Cumulative QC Chart** report for the selected results.

For information on the tabs, see *Print screen* on page E-68.

Date Range area

Date Range Select the **Date Range** check box to print the report for a range of dates. If selected, the **Start** and **End** date text boxes are activated. The date format (dd/mm/yy, mm/dd/yy, yy/dd/mm or yy/mm/dd) is defined in the **Date** list box on **Utility** > **System**.

See *Date and Time Setting area* on page E-362.

Start Type the first date of the date range to be printed on the report.

End Type the last date of the date range to be printed on the report.

Buttons

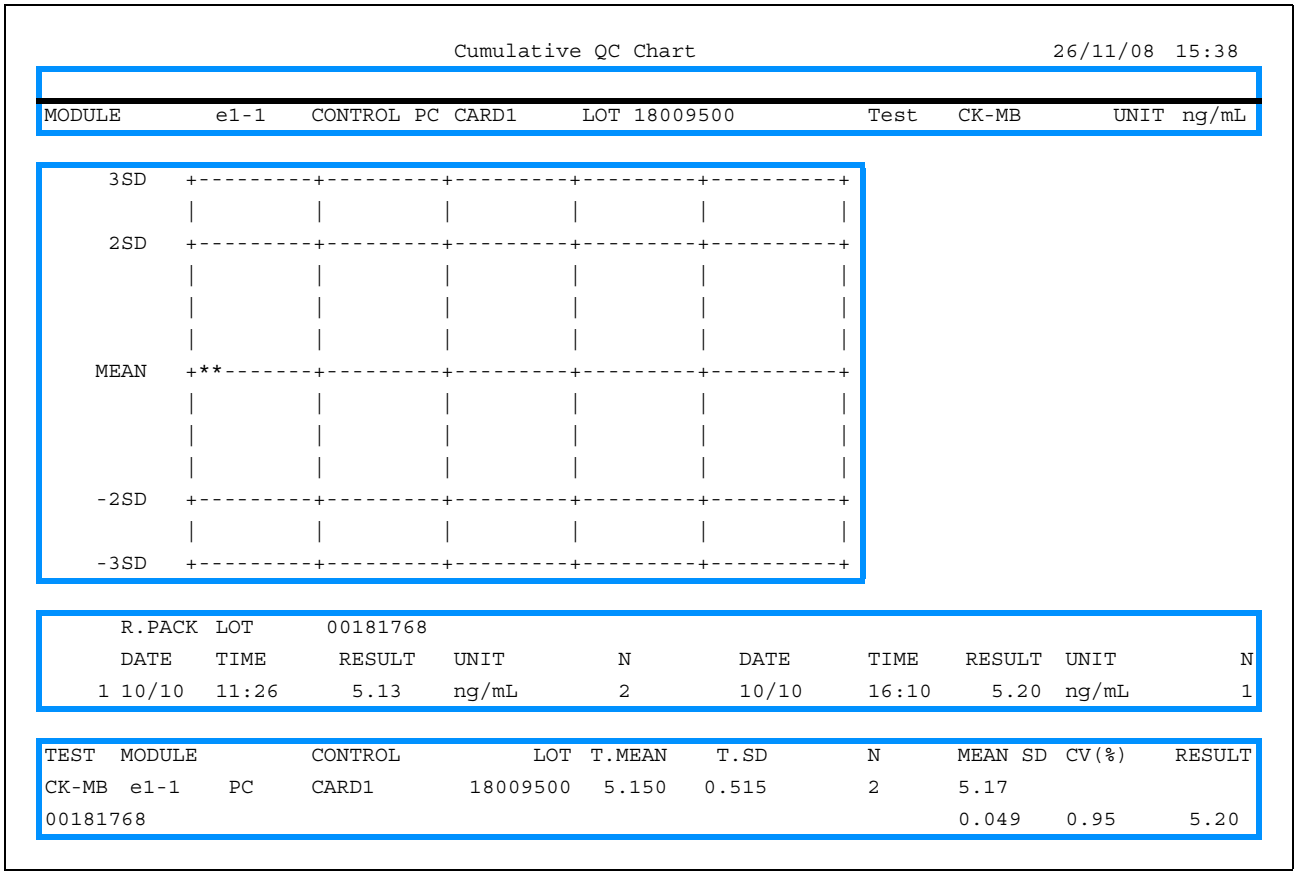
Print Choose this button to send the selected report to the printer and to store it in the print buffer.

Preview Choose **Preview** and then **View** to display a preview of the currently selected report without printing the report.

View Choose this button to view the lists and reports currently in the print buffer and also to write them to disk.

For more information, see:
Print View window on page E-70
Media Write window on page E-74

Cumulative QC Chart report



```
                              Cumulative QC Chart                          26/11/08  15:38

MODULE        e1-1    CONTROL PC CARD1     LOT 18009500          Test    CK-MB        UNIT  ng/mL

     3SD   +---------+---------+---------+---------+----------+
           |         |         |         |         |          |
     2SD   +---------+---------+---------+---------+----------+
           |         |         |         |         |          |
           |         |         |         |         |          |
           |         |         |         |         |          |
    MEAN   +**-------+---------+---------+---------+----------+
           |         |         |         |         |          |
           |         |         |         |         |          |
           |         |         |         |         |          |
    -2SD   +---------+---------+---------+---------+----------+
           |         |         |         |         |          |
    -3SD   +---------+---------+---------+---------+----------+

      R.PACK  LOT      00181768
      DATE    TIME      RESULT   UNIT          N         DATE      TIME    RESULT  UNIT          N
    1 10/10   11:26       5.13    ng/mL         2         10/10     16:10     5.20  ng/mL         1

TEST  MODULE          CONTROL           LOT  T.MEAN    T.SD        N       MEAN SD  CV(%)     RESULT
CK-MB  e1-1    PC     CARD1        18009500   5.150   0.515        2       5.17
00181768                                                                  0.049    0.95       5.20
```

Figure E-88 Cumulative QC Chart report

Cumulative QC Chart report explanation

The first line of the report displays the report name and the date and time the report was printed.

The actual **Cumulative QC Chart** report is divided into four sections:

- Header
 - See *Header*.
- QC chart
 - See *Chart*.
- Results section
 - See *Results*.
- Statistics section
 - See *Statistics*.

Header

MODULE This field displays the name of the module and measuring channel for which the QC statistic is displayed.

CONTROL This field displays the name of the selected control.

LOT This field displays the lot number of the selected control.

TEST This field displays the short test name of the selected test.

UNIT This field displays the unit of measure for the selected control.

Chart

The values (in SD) of the controls measured are plotted on the Y-axis and time on the X-axis. All points should lie within the ±3SD range. If a point falls outside of this range, corrective action is required.

Each point on the chart represents one individual control result for a test.

Results

The results section (table) displays information about the QC results displayed in the chart.

```
...

      R.PACK  LOT      00181768
      DATE    TIME      RESULT   UNIT         N         DATE      TIME    RESULT  UNIT         N
    1 10/10   11:26       5.13   ng/mL        2         10/10     16:10     5.20  ng/mL        1
...
```

Figure E-89 Cumulative QC Chart report - results

R.PACK LOT This field displays the lot number of the **cobas e** pack used for the QC measurement. For each lot a separate result and statistics section is displayed.

For **cobas c** packs no lot number is displayed.

DATE This column displays the date the control run was accumulated.

TIME This column displays the time the control run was accumulated.

RESULT This column displays the calculated result for this accumulation.

- If Mean-R is selected as accumulation method this is the mean value.
- If X-R is selected as accumulation method, this is an individual result.

See *Accumulation methods for QC measurement data* on page B-199.

If the result is not in the range MEAN ±2 SD, an asterisk (*) is printed to the right of the result.

N This field displays the number of QC measurements represented in the accumulation.

Statistics

The statistics section (table) displays statistical data about the QC results displayed in the chart.

```
...

TEST  MODULE          CONTROL          LOT  T.MEAN    T.SD        N      MEAN SD  CV(%)    RESULT
CK-MB  e1-1    PC     CARD1        18009500   5.150   0.515        2      5.17
00181768                                                                0.049    0.95      5.20
...
```

Figure E-90 Cumulative QC Chart report - statistics

TEST This column displays the short test name of the selected test.

MODULE This column displays the name of the module and measuring channel for which the QC statistic is displayed.

CONTROL This column displays the name of the selected control.

LOT This column displays the lot number of the selected control.

T.MEAN This column displays the target mean for the selected test and control level, as specified on **QC** > **Install**.

The target mean may be different for different **cobas e** pack lots, even if the same control lot is used. Thus, for each **cobas e** pack lot a separate result and statistics section is displayed.

T.SD This column displays the target standard deviation for the selected test and control level, as specified on **QC** > **Install**.

N This column displays the number of control results which are evaluated in the statistic.

MEAN This column displays the calculated mean for the set (N) of individual control values.

SD This column displays the calculated standard deviation of all accumulations for this test.

CV(%) This column displays the calculated coefficient of variation (CV) of all accumulations for this test.

RESULT (on the bottom right) This column displays the most recent accumulated result. If Mean-R was chosen on **Utility** > **System** (**Page 1/4**) > **QC Setting**, this is the mean value. If X-R was chosen, this may be an individual result.

See *QC Setting window* on page E-387.

Cumulative QC List

➔ **Print** (global button) > **QC** > **Cumulative QC List**

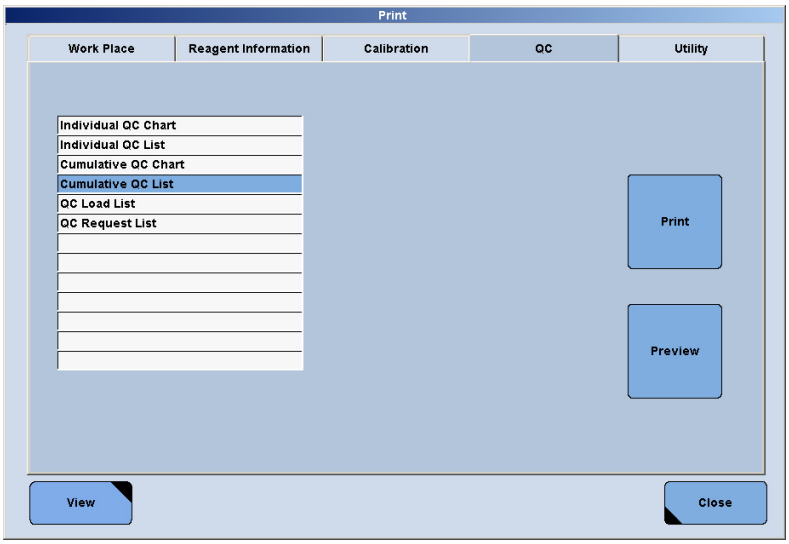


Figure E-91 Cumulative QC List print screen

Prior to printing or viewing this report, select the desired data on **QC** > **Cumulative**.

Select **Cumulative QC List** from the report list to print the **Cumulative QC List** report.

For information on the tabs, see *Print screen* on page E-68.

Buttons

Print Choose this button to send the selected report to the printer and to store it in the print buffer.

Preview Choose **Preview** and then **View** to display a preview of the currently selected report without printing the report.

View Choose this button to view the lists and reports currently in the print buffer and also to write them to disk.

For more information, see:
Print View window on page E-70
Media Write window on page E-74

Cumulative QC List report

```
                              Cumulative QC List           26/11/08          15:40

TEST      MODULE      CONTROL      LOT   T.MEAN     T.SD  N   MEAN SD    CV(%) RESULT
AMY-P       C       PNU         17349900     38.3      2.3  1  38.600
                                                                                38.60
ASTLP       C       PNU         17349900     44.6      2.7  1  45.200
                                                                                45.20
CK-MB       e1-1    PC CARD1    18009500    5.150    0.515  2    5.17
00181768                                                        0.049     0.95    5.20
CK-MB       e1-1    PC CARD2    18009600    58.50     5.85  2   55.80
00181768                                                        0.025     0.04   55.78
CK-MB       e1-2    PC CARD1    18009500    5.150    0.515  2    5.16
00181768                                                        0.013     0.26    5.15
CK-MB       e1-2    PC CARD2    18009600    58.50     5.85  2   55.89
00181768                                                        0.075     0.13   55.84
UA2         C       Urine QC    12345         238       12  1   95.00
                                                                                95.0
```

Figure E-92 Cumulative QC List report

Cumulative QC List report explanation

Date, Time The date and time the report was printed appears to the right of the report name.

TEST This column displays the short test name of the selected test of the **cobas c** pack or **cobas e** pack used for the control measurement. For **cobas e** packs the lot number is displayed below the short test name.

MODULE This field displays the name of the module and measuring channel in which QC was performed.

CONTROL This field displays the name of the selected control, as specified on **QC** > **Install**.

LOT This field displays the lot number of the selected control, as specified on **QC** > **Install**.

T.MEAN This column displays the target mean for the selected test and control level, as specified on **QC** > **Install**.

T.SD This column displays the target standard deviation for the selected test and control level, as specified on **QC** > **Install**.

N This column displays the number of accumulations.

MEAN This column displays the calculated mean of accumulated control values for each test.

SD This column displays the calculated standard deviation of accumulated control values for each test.

CV(%) This column displays the calculated coefficient of variation (CV) of accumulated control values for each test.

RESULT This column displays the most recent accumulated result. If Mean-R was chosen on **Utility** > **System** (**Page 1/4**) > **QC Setting**, this is the mean value. If X-R was chosen, this may be an individual result.

See *QC Setting window* on page E-387.

QC Load List

➔ **Print** (global button) > **QC** > **Load List**

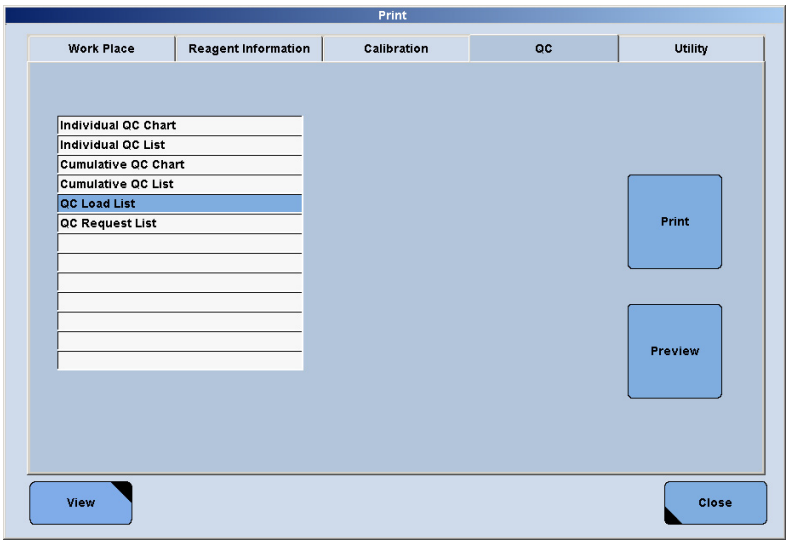


Figure E-93 QC Load List print screen

Select this item from the report list to print the **QC Load List**. If no criteria are selected, default QC controls will be printed on the **QC Load List** report.

For information on the tabs, see *Print screen* on page E-68.

Buttons

Print Choose this button to send the selected report to the printer and to store it in the print buffer.

Preview Choose **Preview** and then **View** to display a preview of the currently selected report without printing the report.

View Choose this button to view the lists and reports currently in the print buffer and also to write them to disk.

For more information, see:
Print View window on page E-70
Media Write window on page E-74

QC Load List report

```
                        QC Load List                                    27/11/08      16:59

----------------------------      System Specific Rack      ----------------------------
AUTOMATIC QC RACK RANGE       0000 -  0000

NAME          LOT              EVENT     VOLUME   R.NO.
PPU           17628700          ----   --------   C0001-2
PNU           17683000          ----   --------   C0001-1

----------------------------        QC After Calib.         ----------------------------
NAME          LOT              EVENT     VOLUME   R.NO.
PC U2         15041800             2       22.0
PC U1         18067700             2       22.0
PC CARD1      18269000             4       60.0   C0005-1
PC CARD2      18269100             4       60.0   C0005-2

----------------------------      Module Specific Rack      ----------------------------
MODULE E1     RACK RANGE         5- 10
NAME          LOT              EVENT     VOLUME   R.NO.
PC U2         15041800             2       22.0
PC U1         18067700             2       22.0
PC CARD1      18269000             4       60.0
PC CARD2      18269100             4       60.0
```

Figure E-94 QC Load List report

QC Load List report explanation

The **QC Load List** displays information about requested measurements for each control. A second part is appended to the list which compiles all QC after calibration measurement requests. A third part provides details specific to individual modules, if module specific racks for **e** 601 modules are defined in the software.

For more information on assigning module specific racks, see *Module Setting tab* on page E-371.

Date, Time The date and time the report was printed appears to the right of the report name.

NAME This column displays the name of each control as defined on **QC** > **Install**.

LOT This column displays the lot number of each control as defined in **QC** > **Install**.

EVENT This column displays the number of times a control will be sampled (**e** 601 only).

VOLUME This column displays the calibrator volume that is needed for measurement (**e** 601 only). The dead volume of the individual sample cup is not considered. The total volume must be calculated by the operator.

For information about the dead volume of the individual sample cups, see *Sample cups and tubes* on page A-116.

R.NO. This column displays the assigned position of each control on the sample rack, if no barcodes are used. If no information is displayed in this column, the instrument expects a barcoded QC on a QC rack.

Control racks are white, with a range of C0001-1 to C0999-5.

Module Specific Rack area This area provides details specific to individual modules.

MODULE This field displays the name of the analytical module to which the control is assigned.

RACK RANGE This field displays the rack range defined on **Utility** > **System** > **Change** (**Rack Assignment** area) > **Module Setting**. These racks will not be transported to other modules than specified.

See *Module Setting tab* on page E-371.

QC Request List

➔ **Print** (global button) > **QC** > **QC Request List**

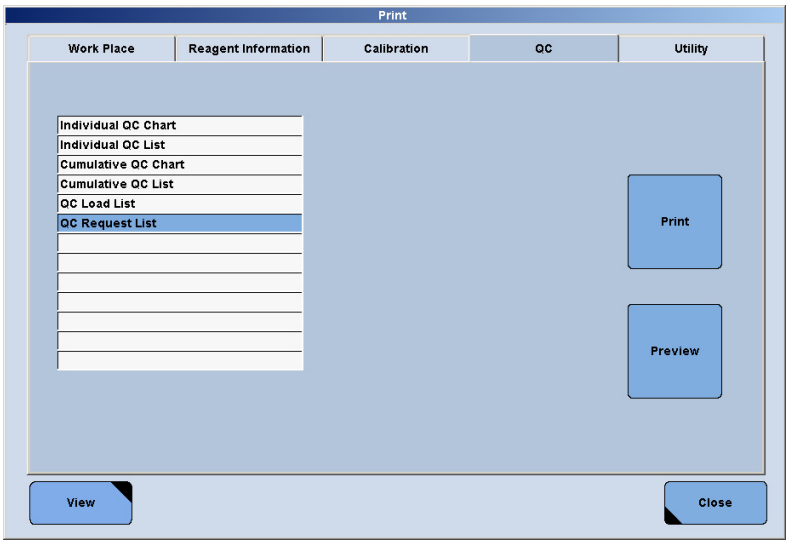


Figure E-95 QC Request List print screen

Select **QC Request List** from the report list to print a detailed list of tests selected for QC. No criteria need to be selected in order to print this report.

For information on the tabs, see *Print screen* on page E-68.

Buttons

Print Choose this button to send the selected report to the printer and to store it in the print buffer.

Preview Choose **Preview** and then **View** to display a preview of the currently selected report without printing the report.

View Choose this button to view the lists and reports currently in the print buffer and also to write them to disk.

For more information, see:
Print View window on page E-70
Media Write window on page E-74

QC Request List report

```
                          QC Request List                 27/11/08      17:01

MODULE C
TEST         LOT
ASTLP        17799500
ASTLP        17349900
CA           17799500
CA           17349900
CHO2I        17799500
CHO2I        17349900

...
...

MODULE E1
TEST         LOT           ORDER
CK-MB        18009600      ch1    ch2
CK-MB        18009500      ch1    ch2
FT4          18067700      ch1    ch2
FT4          15041800      ch1    ch2
HCG-BETA     18067700      ch1    ch2
HCG-BETA     15041800      ch1    ch2
MYO          18009600      ch1    ch2
MYO          18009500      ch1    ch2
TSH          18067700      ch1    ch2
TSH          15041800      ch1    ch2
```

Figure E-96 QC Request List report

QC Request List report explanation

The **QC Request List** displays information about the requested measurement for each test and module.

Date, Time The date and time the report was printed appears to the right of the report name.

MODULE This field displays the name of the module for which QC has been requested.

TEST This column displays the short test name for the application.

LOT This column displays the lot number of the control for which QC has been requested. An asterisk (*) next to the LOT number indicates that this is a **Stand By Bottle QC** request.

ORDER (e 601) This column displays for which measuring channels the controls are requested.

Possible values are ch1 (the control was requested only for channel 1), ch2 (only channel 2), and ch1 ch2 (the control was requested for both channels).

Utility print screen

➔ **Print** (global button) > **Utility**

The Utility print screen displays a list of reports relating to the **Utility** menu. The screen changes depending on the report selected.

Alarm Trace

➔ **Print** (global button) > **Utility** > **Alarm Trace**

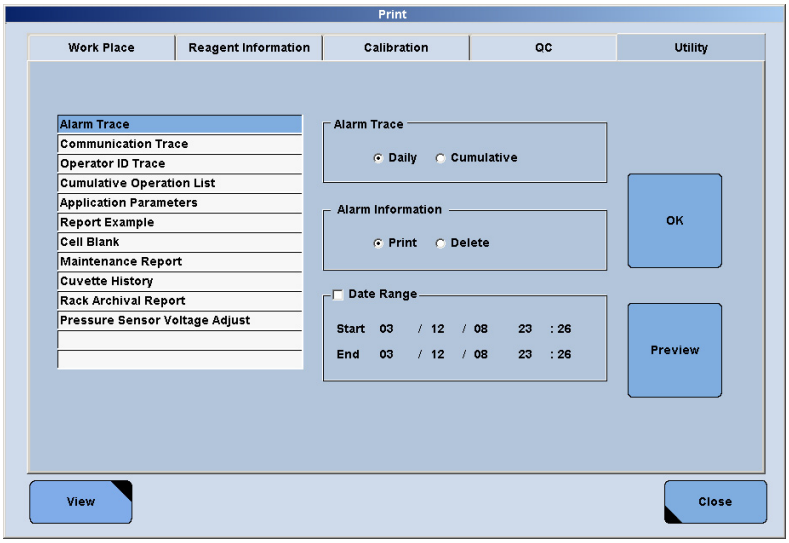


Figure E-97 Alarm Trace print screen

Select **Alarm Trace** from the report list to print or delete the **Daily** or **Cumulative Alarm Trace**.

For information on the tabs, see *Print screen* on page E-68.

The alarm trace report may consist of up to 50 pages. Be sure to set a date range to print only the alarms within the specified date range.

Alarm Trace area

Daily Select **Daily** to perform the function selected in the **Alarm Information** area for **Daily Alarm Trace**.

Cumulative Select **Cumulative** to perform the function selected in the **Alarm Information** area for **Cumulative Alarm Trace**.

Alarm Information area

Print Select **Print** to print the **Daily** or **Cumulative Alarm Trace** selected in the **Alarm Trace** area.

Delete Select **Delete** to delete the **Daily** or **Cumulative Alarm Trace** selected in the **Alarm Trace** area.

When the **Delete** option is selected, the **Date Range** area is not displayed.

Date Range area

Date Range Select the **Date Range** check box to print the report for a range of dates. If selected, the **Start** and **End** date text boxes are activated. The date format (dd/mm/yy, mm/dd/yy, yy/dd/mm or yy/mm/dd) is defined in the **Date** list box on **Utility** > **System**.

See *Date and Time Setting area* on page E-362.

The alarm trace report may consist of up to 50 pages. Be sure to set a date range to print only the alarms within the specified date range.

Start Type the first date and time of the date range to be printed on the report.

If **Cumulative** is selected in the **Alarm Trace** area, the hour and minute text boxes are disabled.

End Type the last date and time of the date range to be printed on the report.

If **Cumulative** is selected in the **Alarm Trace** area, the hour and minute text boxes are disabled.

Buttons

OK Choose this button to perform the function (**Print** or **Delete**) specified in the **Alarm Information** area.

Preview Choose **Preview** and then **View** to display a preview of the currently selected report without printing the report.

View Choose this button to view the lists and reports currently in the print buffer and also to write them to disk.

For more information, see:
Print View window on page E-70
Media Write window on page E-74

Daily Alarm Trace report

```
                              Daily Alarm Trace                          21/10/08   18:14

 21/10   14:10      5  1  E   01-003-0000-000   STOP
 21/10   14:10    628  1  E   11-003-0000-000   STOP
 21/10   14:10      3  1  E   15-002-0000-000   STOP
 21/10   14:04      4  1  E   01-007-0000-000   Rack Supply Complete
 21/10   13:58      4  1  A   01-333-0003-115   ISE Internal Ref. Error
 21/10   13:58      4  1  A   01-334-0003-115   ISE Noise
 21/10   13:58      4  1  A   01-333-0002-115   ISE Internal Ref. Error
 21/10   13:58      4  1  A   01-334-0002-115   ISE Noise
 21/10   13:58      4  1  A   01-333-0001-115   ISE Internal Ref. Error
 21/10   13:58      4  1  A   01-334-0001-115   ISE Noise
 21/10   13:53      4  1  A   01-478-0012-003   Abnormal Probe sucking
 21/10   13:52    621  1  E   11-502-0000-000   Restart
 21/10   13:52      4  1  E   01-502-0000-000   Restart
 21/10   13:52      3  1  E   15-001-0000-000   Start
 21/10   13:48      4  3  A   01-403-0008-018   Sample Short
 21/10   13:47      4  3  A   01-402-0008-030   Sample Short
 21/10   13:45    621  1  E   11-502-0000-000   Restart
 21/10   13:45      4  1  E   01-502-0000-000   Restart
 21/10   13:45      3  1  E   15-001-0000-000   Start
 21/10   13:41      4  1  R   01-001-0000-033   Inc. Bath Water Level Sensor
 21/10   13:41    524  1  E   11-510-0000-000   Change to Operation Request
 21/10   13:41    521  1  E   01-510-0000-000   Change to Operation Request
 21/10   13:41    521  1  E   11-509-0000-000   Change to Waiting For Operation Request
```

Figure E-98 Daily Alarm Trace report

Daily Alarm Trace report explanation

Date, Time — The date and time the report was printed appears to the right of the report name.

Alarm Date and Time — The first 2 columns list the date (as defined on the **Utility** > **System** screen) and time (hh:mm) when the alarm occurred.

Analyzer Status Code — The third column displays a code for each alarm representing the status of the system when the alarm occurred.

Frequency — The fourth column displays the number of successive cycles during which each alarm has occurred since power On.

Alarm (A), Retry (R) or Event Information (E) — The letter A in the fifth column indicates an instrument alarm. The letter R indicates a retry code.

Alarm Code — The sixth column indicates the alarm codes for the alarms that occurred. The alarm code is broken into 4 parts. The first part indicates the module ID. The second part indicates the major (type) alarm. The third part indicates the minor (number) alarm and the fourth part indicates the occurrence time within the time period (cycle). The alarm message appears to the right of each code.

Cumulative Alarm Trace report

```
                                  Cumulative Alarm Trace            04.12.2008      19:08

...
                         11-501-0000-001    Sleep
                         15-013-0000-001    Auto End 1
                         01-501-0000-001    Sleep
                         15-013-0000-001    Auto End 1
                         15-039-0000-001    Wake Up
04/12/08  00:00  07:50  R01-022-0000-002    Cycle Recovery?c501)
                         01-021-0000-001    Cycle Recovery?SU)
                        E15-042-0000-001    Wake Up (from Core)
03/12/08  00:00  18:40  A15-501-0005-001    Reagent Registration Error
                         15-501-0004-001    Reagent Registration Error
                         01-130-0001-003    Inc. Exchange Interrupted(Ecotergent)
                         11-581-0003-001    Feeder
                         15-034-0001-229    Waste Reservoir Full
                         15-513-0781-002    Calibration with expired reagents
                         01-083-0880-001    Calibration Error
                         15-034-0001-426    Waste Reservoir Full
                         01-433-0003-009    Sample Short
                         15-513-0781-004    Calibration with expired reagents
                         01-083-0880-001    Calibration Error
                         02-342-0001-001    Probe Wash Short
                         02-342-0001-001    Probe Wash Short
                        R01-001-0000-008    Inc. Bath Water Level Sensor
                         01-022-0000-006    Cycle Recovery? (c501)
                         01-021-0000-004    Cycle Recovery? (SU)
                         01-001-0000-005    Inc. Bath Water Level Sensor
                         01-001-0000-001    Inc. Bath Water Level Sensor
                         01-022-0000-002    Cycle Recovery?c501)
                         01-021-0000-001    Cycle Recovery?SU)
                        E15-003-0000-002    Maintenance
                         01-632-0000-001    Reagent Cassette Dump
                         15-011-0000-010    Reagent Disk Cover Close
                         01-611-0000-005    Reagent Cassette Loading
                         01-631-0000-001    Reagent Cassette Unloading
                         15-001-0000-002    Start
```

Figure E-99 Cumulative Alarm Trace report

Cumulative Alarm Trace report explanation

Date, Time The date and time the report was printed appears to the right of the report name.

Power Up time The first 2 columns list the date and time (hh:mm) the instrument is powered up, as determined by the realtime clock. If the instrument is powered up continuously, the end of the day is determined by the realtime clock.

Last Alarm Time The third column displays the time (hh:mm) at which the last alarm occurred, as determined by the realtime clock.

Alarm, Retry, or Event Information The letter A in the fourth column indicates an instrument alarm. The letter R indicates a retry code. The letter E indicates an event code.

Alarm Code The fifth column indicates the alarm codes for the alarms that occurred. The alarm code is broken into 4 parts. The first part indicates the module ID. The second part indicates the major (type) alarm. The third part indicates the minor (number) alarm and the fourth part indicates the occurrence time within the day. The alarm message appears to the right of each code.

Communication Trace

➔ **Print** (global button) > **Utility** > **Communication Trace**

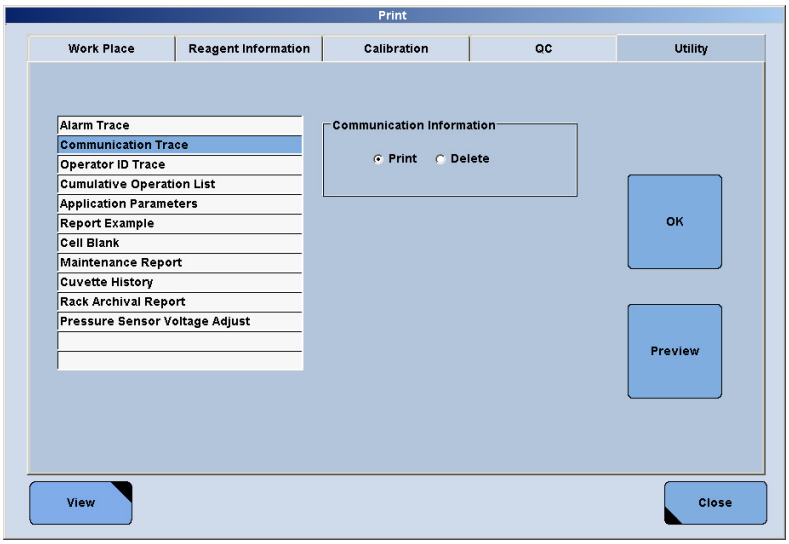


Figure E-100 Communication Trace print screen

Select this item from the report list to print or delete the communication trace.

For information on the tabs, see *Print screen* on page E-68.

Communication Trace must be enabled on **Utility** > **System** (**Page 1/4**) > **Host Comm.**

See *Host Communication Setting window* on page E-376.

Communication Information area

Print Choose **Print** to send the selected report to the printer and to store it in the print buffer.

Delete Choose **Delete** to delete the communication trace.

Buttons

OK Choose this button to perform the function (**Print** or **Delete**) specified in the **Communication Information** area.

Preview Choose **Preview** and then **View** to display a preview of the currently selected report without printing the report.

View Choose this button to view the lists and reports currently in the print buffer and also to write them to disk.

For more information, see:
Print View window on page E-70
Media Write window on page E-74

System Communication Trace report

```
                                System Communication Trace        07/10/08      09:44

09/30   12:16:11.340   S   <STX>1H|\^&|||cobas6000^1|||||host|RSUPL^BATCH|P|1<CR>P|1||
                           |||||U||||||^<CR>O|1|PNU                    |2002^3001^1^^QC
                           ^SC|^^^989^\^^^990^\^^^991^|||||||Q||||1|||||||200809261000
                           25|||F<CR>C|1|I|^^^^|G<CR>R|1|^^^989/|       |mmol/L||A||||
                           admin|||ISE1<CR>C|1|I|19|<ETB>C8<CR><LF>
09/30   12:16:11.665   R   <ACK>
09/30   12:16:11.665   S   <STX>2I<CR>R|2|^^^990/|      |mmol/L||A||||admin |||ISE1<CR
                           >C|1|I|19|I<CR>R|3|^^^991/|      |mmol/L||A||||admin |||ISE
                           1<CR>C|1|I|19|I<CR>L|1|N<CR><ETX>6B<CR><LF>
09/30   12:16:11.860   R   <ACK>
09/30   12:16:11.860   S   <EOT>
09/30   12:56:17.560   S   <ENQ>
09/30   12:56:17.600   R   <ACK>
09/30   12:56:17.600   S   <STX>1H|\^&|||cobas6000^1|||||host|TSREQ^REAL|P|1<CR>Q|1|^^
                                        000178^0^5052^5^^S1^SC||ALL||||||||O<CR>L|1
                           |N<CR><ETX>A8<CR><LF>
09/30   12:56:17.905   R   <ACK>
09/30   12:56:17.910   S   <EOT>
09/30   12:56:17.960   R   <ENQ>
09/30   12:56:17.960   S   <ACK>
09/30   12:56:18.195   R   <STX>1H|\^&|||host^1|||||H7600|TSDWN^REPLY|P|1<CR>P|1||||||
                           |U||||||<CR>O|1|                 000178|0^5052^5^^S1^SC|^^^9
                           89^\^^^990^|R||20080930124500||||A||||1|||||||||O<CR>C|1|L
                           |^^^^|G<CR>L|1|N<CR><ETX>F4<CR><LF>
09/30   12:56:18.200   S   <ACK>
09/30   12:56:18.240   R   <EOT>
09/30   13:00:11.475   S   <ENQ>
```

Figure E-101 System Communication Trace report

Communication Trace report explanation

For information concerning interpretation of this report, contact Roche service representative.

Operator ID Trace

The password protection function, set by the Roche service representative, must be on before this trace can be accomplished.

➔ **Print** (global button) > **Utility** > **Operator ID Trace**

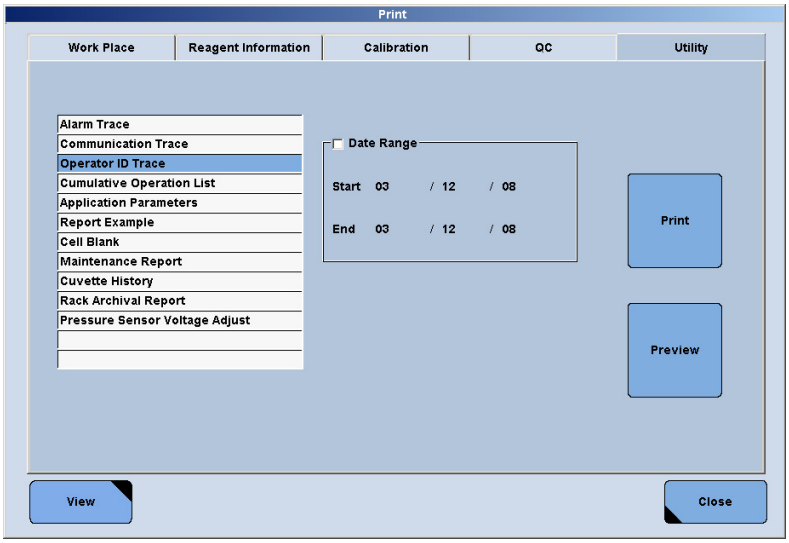


Figure E-102 Operator ID Trace print screen

Select this item from the report list to print the **Operator ID Trace**.

For information on the tabs, see *Print screen* on page E-68.

Date Range area

Date Range Select the **Date Range** check box to print the report for a range of dates. If selected, the **Start** and **End** date text boxes are activated. The date format (dd/mm/yy, mm/dd/yy, yy/dd/mm or yy/mm/dd) is defined in the **Date** list box on **Utility** > **System**.

See *Date and Time Setting area* on page E-362.

Start Type the first date of the date range to be printed on the report.

End Type the last date of the date range to be printed on the report.

Buttons

Print Choose this button to send the selected report to the printer and to store it in the print buffer.

Preview Choose **Preview** and then **View** to display a preview of the currently selected report without printing the report.

View Choose this button to view the lists and reports currently in the print buffer and also to write them to disk.

For more information, see:
Print View window on page E-70
Media Write window on page E-74

Operator ID Trace report

```
                          Operator ID Trace                  21/10/08        18:14

                    TERM   21/02/08 - 21/10/08

DATE        OP.ID   LOGON  LOGOFF    OP.ID     LOGON  LOGOFF    OP.ID   LOGON   LOGOFF
21/02/08    sup1    09:02  **
22/02/08    sup1    09:03  16:03
25/02/08    sup1    08:15  15:23     sup1      15:23  17:57
26/02/08    sup1    09:24  **
27/02/08    sup1    08:41  09:48     ADM       09:48  09:48     ADM     09:48   09:54
            ADM     10:08  10:10     ADM       11:20  **        sup1    18:18   **
28/02/08    ADM     08:20  11:20     sup1      11:43  **        sup1    16:32
29/02/08    sup1           12:27     sup1      13:23  **
```

Figure E-103 Operator ID Trace report

Operator ID Trace report explanation

The Operator ID Trace report indicates the dates and times each operator has logged on and logged off the system for the specified date range. Up to 1000 records can be stored.

Date, Time The date and time the report was printed appears to the right of the report name.

TERM This field displays the date range specified for the report.

DATE This column displays the date of the logon/logoff activity.

OP. ID This column displays the identification of the operator logged onto the system for the given date.

LOGON This column displays the time the operator logged onto the system.

LOGOFF This column displays the time the operator logged off the system.

A double asterisk (**) appears in the Logoff column when logoff occurs automatically by the system instead of the operator logging off (for example, during a power loss).

Cumulative Operation List

➔ **Print** (global button) > **Utility** > **Cumulative Operation List**

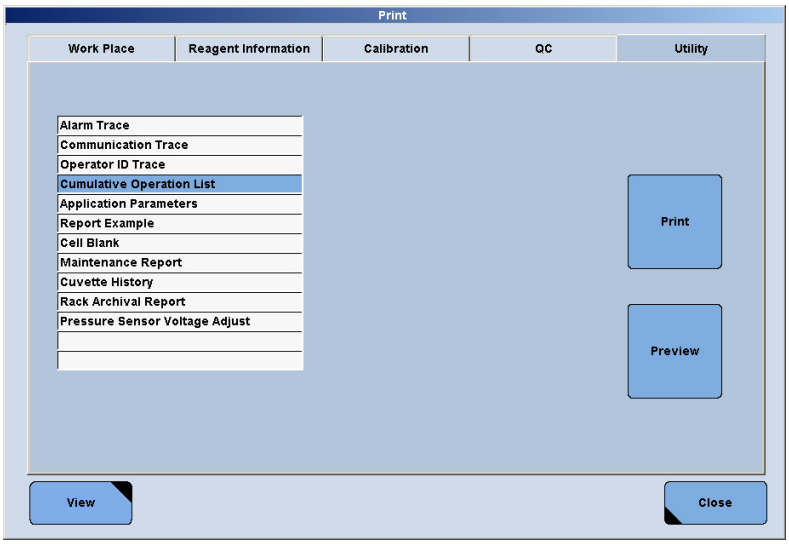


Figure E-104 Cumulative Operation List print screen

Select this item from the report list to print the **Cumulative Operation List**. No criteria need to be selected in order to print this report.

For information on the tabs, see *Print screen* on page E-68.

Buttons

Print Choose this button to send the selected report to the printer and to store it in the print buffer.

Preview Choose **Preview** and then **View** to display a preview of the currently selected report without printing the report.

View Choose this button to view the lists and reports currently in the print buffer and also to write them to disk.

For more information, see:
Print View window on page E-70
Media Write window on page E-74

Cumulative Operations List report

```
                              Cumulative Operations List                04/12/08        19:11

1. POWER ON TIME                    6176           HOURS
2. OPERATION                        2117           HOURS
3. TEST COUNT
   MODULE C
   TEST      CODE      ROUTINE    CALIB.   CONTROL     RERUN    STAT   TOTAL
   CRPLX     0019           31        24        15         5       1      76
   CKMBL     0060           14        50        12        13       0      89
   ALBS2     0128           39        12         0        26       0      77
   LDIP2     0147            0         0         0         0       0       0
   GGTI2     0220          139        36        72        36      13     296
   ALBU2     0253           17        30         5         5       0      57
   ...
   ------------------------------------------------------------------------------------------
   TOTAL                 3666      5278      2115      1697     213   12969

   MODULE E1-1
   TSH       0001           41       110        79         6       4     240
   T4        0002           29        35        35         3       2     104
   FT4       0004           35       102        78         4       0     219
   TN-T      0039           20        32        24         2       1      79
   CK-MB     0043            7        19        26         0       0      52
   ...
   ------------------------------------------------------------------------------------------
   TOTAL                  182       438       370        22      12    1024

   MODULE E1-2
   TSH       0001           41       104        85        11       4     245
   T4        0002           30        31        33         1       3      98

                              Cumulative Operations List                04/12/08        19:11

   TEST      CODE      ROUTINE    CALIB.   CONTROL     RERUN    STAT   TOTAL
   FT4       0004           35        98        79         1       4     217
   TN-T      0039           24        32        22         3       0      81
   CK-MB     0043            5        11        24         0       2      42
   ...
   ------------------------------------------------------------------------------------------
   TOTAL                  193       411       361        29      17    1011

   TOTAL                 4041      6127      2846      1748     242   15004

4. NO.OF SAMPLE      MODULE              ROUTINE     RERUN          STAT          TOTAL
                     C                      2872      1449           183           4504
                     e1-1                    185        23            12            220
                     e1-2                    195        30            17            242
                ------------------------------------------------------------------------
                     TOTAL                  3252      1502           212           4966

5. NO.OF DETECTION CH                  MODULE     NO.AFTERCLEAR          TOTAL
                                         e1-1             45882          45882
                                         e1-2             45364          45364
```

Figure E-105 Cumulative Operations List report

Cumulative Operations List report explanation

The **Cumulative Operations List** report gives the test count of the number of each test performed by the system, as well as power on time and time in Operation.

Date, Time The date and time the report was printed appears to the right of the report name.

POWER ON TIME This field indicates the cumulative number of hours the instrument has been powered on. This includes standby and operation.

OPERATION This field indicates the cumulative number of hours of Operation.

TEST COUNT This table displays the module, test name, application code, and test count totals for routine samples, calibrators, controls, and rerun, STAT and total samples. The last column displays the total number of tests performed.

NO. OF SAMPLE This line displays the module, the total number of routine, rerun and STAT samples, and the total number of all samples analyzed.

NO. OF DETECTION CH This line indicates the total number of measurements each measuring channel has performed.

NO.AFTER CLEAR Test count for each measuring channel after reset, which should be cleared by the Roche service representative when the measuring channel is exchanged.

Application Parameters

➔ **Print** (global button) > **Utility** > **Application Parameters**

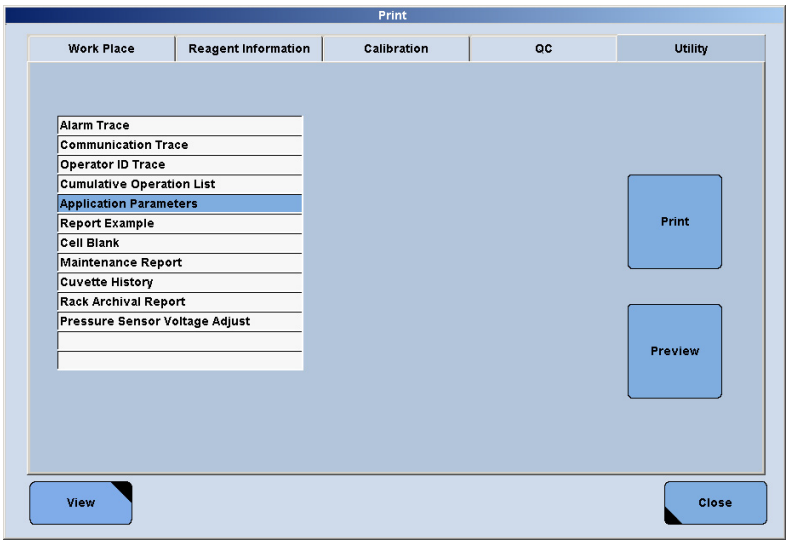


Figure E-106 Application Parameters print screen

Prior to printing or viewing this report, select the desired data from the **Test** list on **Utility** > **Application**.

Select **Application Parameters** from the report list to print the application parameters for the selected test(s).

For information on the tabs, see *Print screen* on page E-68.

Buttons

Print Choose this button to send the selected report to the printer and to store it in the print buffer.

Preview Choose **Preview** and then **View** to display a preview of the currently selected report without printing the report.

View Choose this button to view the lists and reports currently in the print buffer and also to write them to disk.

For more information, see:
Print View window on page E-70
Media Write window on page E-74

Application Parameters report

```
                        Application Parameters             04.12.2008      19:00

TEST NO.                          141
TEST NAME                         TSH
TEST CODE                         001
MODULE                              E
SAMPLE TYPE                 Ser/Pl

<< ANALYZE >>

SAMPLE VOLUME                      49
DEFAULT DIL.RATIO(1ST)              1
DEFAULT DIL.RATIO(RERUN)            1
CAP OPEN/CLOSE MODE         PIPETTING

<< RANGE >>

UNIT                            uIU/mL

REPORT NAME             TSH

TEST PRIORITY                  NORMAL
AUTOMATIC RERUN                   YES
Control Interval                    0
REPEAT LIMIT (LOW)             -99999
REPEAT LIMIT (HIGH)            999999

<< CALIB. >>

DUPLICATE LIMIT                    10
AUTO MASKING                      YES
AUTO CALIB. TIMEOUT               YES
RACK PACK STABILITY                NO
          (DAYS)                   99
LOT STABILITY                      NO
          (DAYS)                   99
AUTO CALIB. QC VIOLATION           NO
          (METHOD)               FULL
          (RULE)                   1s
          (CONTROL1)
          (CONTROL2)
          (CONTROL3)
```

Figure E-107 Application Parameters report

Application Parameters report explanation

The application parameters listed in this report depend on the kind of test(s) selected from the **Test** list on **Utility** > **Application**.

For more information on application parameters, see *Application screen* on page E-484.

Report Example

➔ **Print** (global button) > **Utility** > **Report Example**

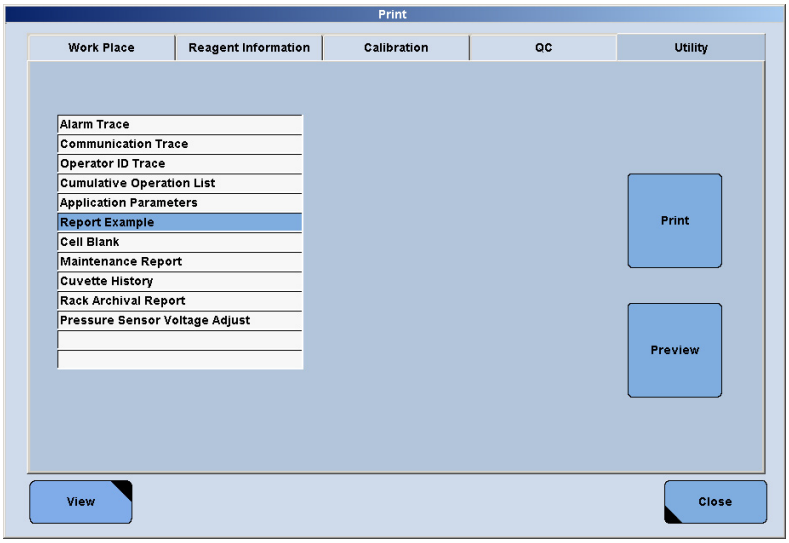


Figure E-108 Report Example print screen

Select this item from the report list to print or view the Report Example. Use this example to view the printing format of patient reports. The printing format is defined on **Utility** > **Report Format**.

👁 See *Report Format screen* on page E-540.

👁 For information on the tabs, see *Print screen* on page E-68.

Buttons

Print Choose this button to send the selected list to the printer and to store it in the print buffer.

Preview Choose **Preview** and then **View** to display a preview of the currently selected report without printing the report.

View Choose this button to view the lists and reports currently in the print buffer and also to write a report to disk.

👁 For more information, see:
Print View window on page E-70
Media Write window on page E-74

Report Example

```
                    ****************************************
                    *        HITACHI AUTOMATIC ANALYZER      *
                    ****************************************
ID            123456789012345678901        DATE            02/09/08 14:25:22
S.NO.         NR       00001-1             OPERATOR ID     &&&&&&
S.TYPE        ******                       Name            ##############################
AGE           100 Y
SEX           M
DRAW DATE     02/02/06
DRAW TIME     14:25
PREDILUTED    NO
TEST          RATIO    COI/MES       RESULT    UNIT      MODULE  EXPECTED VALUE           ALARM
TRIGL         ***                     999999 H  mmol/L    C       (-999999-9999999)        ******
Glucose       ***                     999999 H  mg/dL     C       (-999999-9999999)        ******
TSH           ***      9999999      9999999 H  uIU/mL    E -1    (-999999-9999999)        ******
LH            ***      9999999      9999999 H  IU/L      E -1    (-999999-9999999)        ******
```

Figure E-109 Patient report example

To edit the printing format of patient reports (including this example), see *Report Format screen* on page E-540.

Cell Blank

➔ **Print** (global button) > **Utility** > **Cell Blank**

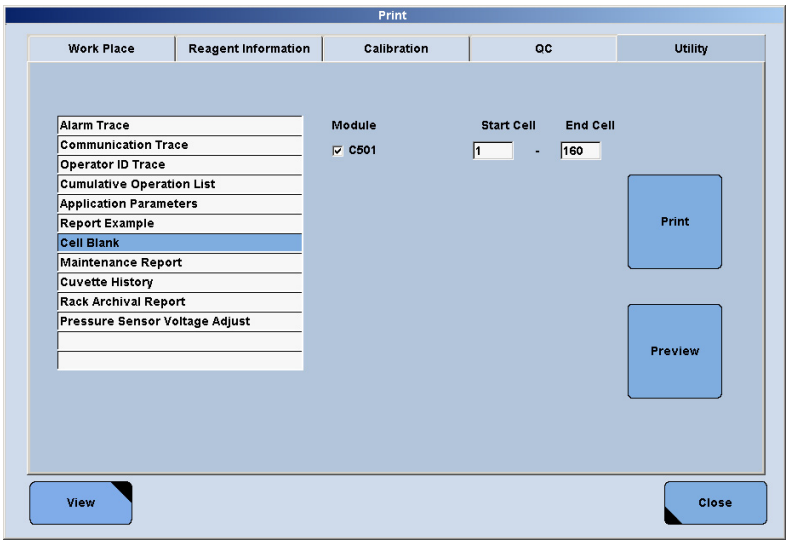


Figure E-110 Cell Blank print screen

Select this item from the report list to print the **Cell Blank Measurements** report.

Module Select the check box for the desired module. If selected, the **Start Cell** and **End Cell** text boxes are activated.

Start Cell End Cell Type the starting and ending cell numbers for each module in the report. The range of each entry for the **c** 501 module is 1 to 160.

For information on the tabs, see *Print screen* on page E-68.

Buttons

Print Choose this button to send the selected report to the printer and to store it in the print buffer.

Preview Choose **Preview** and then **View** to display a preview of the currently selected report without printing the report.

View Choose this button to view the lists and reports currently in the print buffer and also to write them to disk.

For more information, see:
Print View window on page E-70
Media Write window on page E-74

Cell Blank Measurements report

```
                                Cell Blank Measurements                 04/12/08      18:25
MODULE   C1
------------------------------      ABORMAL CELL LIST      ----------------------------------

27/11/08   17:03 -------------        WAVELENGTH (nm)       ----------------------------------
CELL NO.     340    376    415    450    480    505    546    570    600    660    700    800

     001   10392   9806   9625   9393   9388   9230   9065   9075   8988   8838   8716   8543
     002   10422   9817   9639   9408   9403   9244   9079   9085   8997   8847   8726   8554
     003   10429   9843   9660   9425   9421   9262   9099   9107   9021   8872   8749   8568
     004   10522   9917   9721   9481   9472   9310   9139   9142   9053   8898   8772   8588
     005   10379   9798   9612   9382   9380   9222   9060   9068   8981   8833   8711   8532
     006   10421   9827   9641   9408   9404   9244   9079   9084   8998   8848   8725   8549
     007   10400   9817   9628   9395   9392   9233   9068   9076   8990   8840   8719   8540
     008   10503   9894   9694   9452   9440   9277   9105   9110   9020   8865   8741   8558
     009   10500   9896   9692   9449   9437   9274   9102   9108   9017   8863   8737   8551
     010   10509   9898   9703   9461   9452   9289   9119   9122   9033   8878   8753   8573
```

Figure E-111 Cell Blank Measurements report

Cell Blank Measurements report explanation

The **Cell Blank Measurements** report displays the absorbance of all 160 reaction cells at all 12 wavelengths for the **c** 501 (P). These absorbance readings are taken with the reaction cells filled with water.

Date, Time The date and time the report was printed appears to the right of the report name.

MODULE This field displays the name of the module on which the test is performed. Only **c** 501 modules are included.

ABNORMAL CELL LIST In case there are cells for which the cell blank measurement yields abnormal results, the numbers of the respective reaction cells are listed here.

Date and Time The date and time (hours:minutes) the last cell blank was performed appear in the upper left corner of the report.

WAVELENGTH (nm) The reaction cell number (CELL NO.) is indicated in the far left column. Absorbance readings of each reaction cell at each of 12 wavelengths (340, 376, 415, 450, 480, 505, 546, 570, 600, 660, 700, and 800) are printed. This information is automatically written to the database as the cells are blanked.

Results for reaction cells must be < 14,000. Normal cell blank values are < 14,000 for all no. 1 cells on all modules and a difference between the no. 1 cell and the cells 2-160 of less than ± 1000 (± 0.1).

For information about the cell blank measurement, see:
To perform a cell blank measurement on page C-78
To view the cell blank measurement results on page C-79

Maintenance Report

➔ **Print** (global button) > **Utility** > **Maintenance Report**

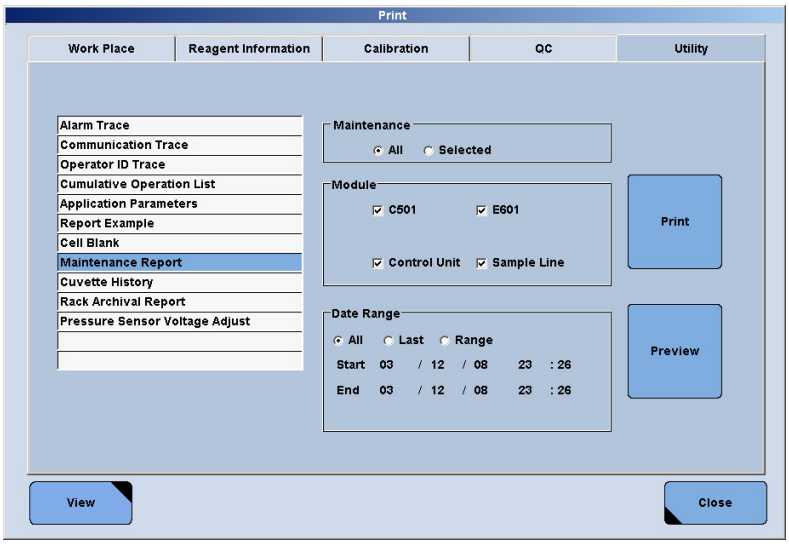


Figure E-112 Maintenance Report print screen

Prior to printing or viewing this report, select the desired **Maintenance Type** from **Utility** > **Maintenance**.

Select **Maintenance Report** from the report list to print a list containing date, time, operator ID, and comments of the selected maintenance actions. Specific maintenance items can be printed on the **Maintenance Report** if previously selected from the **Maintenance** Item list on **Utility** > **Maintenance**.

For information on the tabs, see *Print screen* on page E-68.

Maintenance area

All Select the **All** option to print the **Maintenance Report** for all maintenance items of the selected **Maintenance Type** performed on the system.

Selected Select the **Selected** option to print the **Maintenance Report** for only the maintenance items selected on **Utility** > **Maintenance**.

Module area

Select the **Module** check box to print the **Maintenance Report** for only the modules selected. Select the appropriate **module** check box. The check boxes available vary depending on your system configuration.

Date Range area

All Select the **All** option to print the **Maintenance Report** for all maintenance performed.

Last Select the **Last** option to print the **Maintenance Report** for only the last maintenance item performed.

Range Select the **Range** option to print the report for a range of dates. If selected, the **Start** and **End** date text boxes are activated. The date format (dd/mm/yy, mm/dd/yy, yy/dd/mm or yy/mm/dd) is defined in the **Date** list box on **Utility** > **System**.

See *Date and Time Setting area* on page E-362.

Start Type the first date and time of the date range to be printed on the report.

End Type the last date and time of the date range to be printed on the report.

Buttons

Print Choose this button to send the selected report to the printer and to store it in the print buffer.

Preview Choose **Preview** and then **View** to display a preview of the currently selected report without printing the report.

View Choose this button to view the lists and reports currently in the print buffer and also to write them to disk.

For more information, see:
Print View window on page E-70
Media Write window on page E-74

Maintenance Report

```
                    Maintenance Report                      04/12/08  19:16

POWER ON TIME                           6249      HOURS
OERATION                                2021      HOURS

MAINTENANCE TYPE:    Maintenance                                  Page     1
MODULE:              C
MAINTENANCE
   DATE      TIME    OP.ID     COMMENTS
Reset
   03/12/08  13:23   admin
   02/12/08  13:49   admin
Rack Reset
   02/12/08  13:31   admin
Photometer Check
*  04/12/08  08:14   sup1
Cell Blank Measurement
   01/12/08  15:25   admin
*  01/12/08  08:42   admin
Incubation Water Exchange
*  04/12/08  08:06   sup1
   01/12/08  16:13   admin
Air Purge
*  04/12/08  17:37   admin
*  04/12/08  08:04   sup1
*  03/12/08  18:02   admin
*  02/12/08  11:42   admin
Wash Reaction Parts
*  01/12/08  08:42   admin
Reagent Prime
*  04/12/08  08:11   sup1
*  01/12/08  08:35   admin
Cell Detergent Prime
Incubator Bath Cleaning
IS Bath Cleaning
Sample Probe Wash
Motor Off
Floppy Disk Utility
Parameter Read/Write
Test Count Write
QC Timer Reset
Probe Check
Reagent Probe Wash
Bead Mixer Rinse
E Module Reagent Wash
Pipetter Air Purge
...
```

Figure E-113 Maintenance report

Maintenance report explanation

The **Maintenance Report** provides a log showing when each maintenance activity on the system was performed. Each maintenance item is listed, followed by the date, the time, the operator ID of the person who initiated the maintenance activity, and any pertinent comments. Activity is presented from most recent to oldest.

Date, Time The date and time the report was printed appears to the right of the report name.

POWER ON TIME This field displays the total time (hours) the system has been powered ON.

OPERATION This field displays the total time (hours) the system has been in operation, i.e., in the Operation mode.

MAINTENANCE TYPE This field displays the type of maintenance activity included in the report. Valid entries include Maintenance and Check.

MODULE This field displays the name of the module on which the maintenance activity was performed. Valid modules include Control Unit and Sample Line. In case of Maintenance Pipe, ------- is printed instead of the name of module.

MAINTENANCE This field displays the name of the maintenance activity.

For more information, see:
Maintenance items on page E-423
Maintenance checks on page E-466

DATE This field displays the date the maintenance activity was performed. When a maintenance item is performed as a part of maintenance pipe, an asterisk (*) is printed next to the date.

TIME This field displays the time (hh:mm) the maintenance activity was performed.

OP. ID This field displays the identification of the operator who initiated the maintenance activity.

COMMENTS This field displays comments corresponding to the maintenance activity performed.

Cuvette History

➔ **Print** (global button) > **Utility** > **Cuvette History**

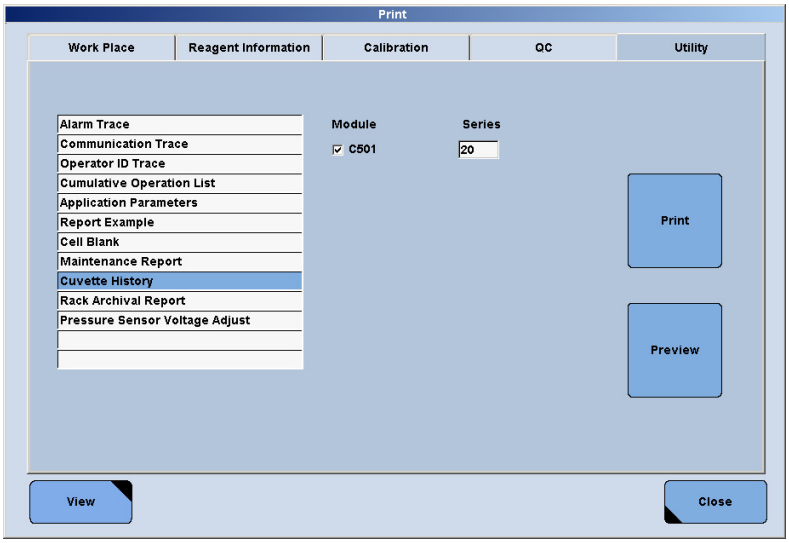


Figure E-114 Cuvette History print screen

Select this item from the report list to print the **Cuvette History** report.

Module Select the check box for the desired module. If selected, the **Series** text box is activated.

Series Type the number (1 to 20) of the series for the reaction cell (cuvette).

A series is one use of every reaction cell on the reaction disk. Series 1 is the oldest use, Series 1 is previous to Series 2, with Series 20 being the most recent.

For information on the tabs, see *Print screen* on page E-68.

Buttons

Print Choose this button to send the selected report to the printer and to store it in the print buffer.

Preview Choose **Preview** and then **View** to display a preview of the currently selected report without printing the report.

View Choose this button to view the lists and reports currently in the print buffer and also to write them to disk.

For more information, see:
Print View window on page E-70
Media Write window on page E-74

Cuvette History report

```
                                    Cuvette History                        28/09/08          14:28

MODULE C
SERIES 15
UNIT  CELL    S.NO.        ID                        TEST           BK/LT    S.TYPE    R.TYPE
    CYCLE 001 TIME 28/09/08 09:37:29
SP    004     N000016                                GGTI2          1771               ---
R     004     N000016                                GGTI2          686025   ------    R1
IS    015     N000015                                ISE            -------  ------    ---
M     012     N000015                                GGTI2          -------  ------    2
M     004     N000016                                GGTI2          -------  ------    2
SP    004     N000016                                GGTI2          1771               ---
R     004     N000016                                GGTI2          686025   ------    R1
IS    015     N000015                                ISE            -------  ------    ---

    CYCLE 002 TIME 28/09/08 09:37:36
SP    003     N000016                                CHO2A          992                ---
R     003     N000016                                CHO2A          681326   ------    R1
R     010     N000015                                TP2            682505   ------    R2
IS    ---     IS           --------------------      --------       -------  ------    ---
M     011     N000015                                CHO2A          -------  ------    2
M     003     N000016                                CHO2A          -------  ------    2

    CYCLE 003 TIME 28/09/08 09:37:47
SP    157     E                          1234514     ALB2              -109           ---
R1    157     E                          1234514     ALB2            670009 ------    R1

    CYCLE 004 TIME 28/09/08 09:37:53
SP    116     E                          1234514     SI                1854           ---
R1    116     E                          1234514     SI              665646 ------    R1
```

Figure E-115 Cuvette History report

Cuvette History report explanation

The **Cuvette History** report displays a list of actions per cycle (like pipetting and mixing) performed in each reaction cell on **c** 501.

Date, Time The date and time the report was printed appears to the right of the report name.

MODULE This field displays the name of the module (**c** 501) on which the actions were performed.

SERIES This field displays the series number (01 to 20) for the actions reported. One series has 160 cycles.

UNIT This column displays the name of the unit that performed the action in the reaction cell.

SP	Sample pipetting unit
R1	Reagent 1 pipetting unit
R2	Reagent 2 pipetting unit
IP	ISE reagent pipetting unit
IS	ISE sipper unit
M1	Ultrasonic mixing unit 1 (R1 ISE mixing)
M2	Ultrasonic mixing unit 2 (R2 mixing)
M3	Ultrasonic mixing unit 3 (R3 mixing)

CELL This column displays the reaction cell number. On **c** 501 (P), the number ranges from 001 to 160.

SAMPLE NO. This column displays the kind of sample or solution that was used.

N	Routine	1 to 60,000
E	Stat	1 to 10,000
IS	Internal Standard	
NR	Rerun	1 to 60,000
ER	Rerun Stat	1 to 10,000
C	Control	1 to 100
S	Calibrator (Standard)	x (standard series 1 to 6) y (pipetting series 1 or 2)
S. Wash	S. Probe Wash	
R. Wash	Reagent Probe Wash	
C. Wash	Cell Wash	
R. Dummy	Reagent Dummy	
-----	Empty	
Clot.Wash	Wash after clot detection	
IS.B	IS supply to IS bath	
IS	IS aspiration	
W1	Washing 1	
W2	Washing 2	
W3	Washing 3	

For patient samples in barcode mode, only the code is displayed. In non-barcode mode the sequence number is attached to code.

For controls the number of the control (1-100) from the **QC** > **Install** screen is attached to the code.

For calibrators the level of the calibrator (Std 1-6) from the **Calibration** > **Install** screen is attached to the code and the number of the replication (1—first pipetting, 2—second pipetting).

ID This field displays the patient identification.

TEST This column displays the short name of the test performed in the reaction cell.

BK/LT This column displays the cell blank value when sample is pipetted and the reagent lot number, when reagent is pipetted in the corresponding reaction cell.

S. TYPE *D* is displayed if sample comes from a dilution cuvette (the sample was automatically diluted).

Samp.S is displayed if sample shortage is detected for a sample cup.

Samp.C is displayed if sample clot is detected for a sample cup.

R.TYPE This column indicates which reagent, diluent, or wash solution type is used in the cell.

R1	Reagent 1
R2	Reagent 2
R3	Reagent 3
Dil	Diluent
D1	Detergent 1
D2	Detergent 2
D3	Detergent 3
W	System water

If a number (1-17) is displayed in this column, it indicates the mixing level of the ultrasonic mixing unit.

1-15	Photometric mixing levels
16	Sample dilution mixing level
17	ISE mixing level

CYCLE The number of the cycle when the action was performed.

TIME Date and time of the cycle when the action was performed.

Rack Archival Report

➔ **Print** (global button) > **Utility** > **Rack Archival Report**

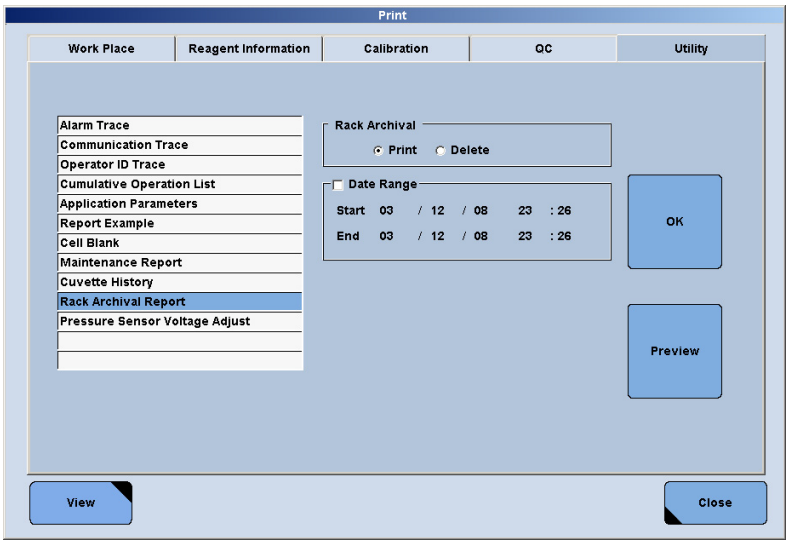


Figure E-116 Rack Archival Report print screen

Select this item from the report list to print or delete the **Rack Archival Report**.

For information on the tabs, see *Print screen* on page E-68.

Rack Archival area

Print **Print**: Choose this option to send the selected report to the printer and to store it in the print buffer.

Delete **Delete**: Choose this option to delete the **Rack Archival Report**.

Date Range area

Date Range Select the **Date Range** check box to print the report for a range of dates. If selected, the **Start** and **End** date text boxes are activated. The date format (dd/mm/yy, mm/dd/yy, yy/dd/mm or yy/mm/dd) is defined in the **Date** list box on **Utility** > **System**.

See *Date and Time Setting area* on page E-362.

Start Type the first date and time of the date range to be printed on the report.

End Type the last date and time of the date range to be printed on the report.

Buttons

OK Choose this button to perform the function (**Print** or **Delete**) specified in the **Rack Archival** area.

Preview Choose **Preview** and then **View** to display a preview of the currently selected report without printing the report.

View Choose this button to view the lists and reports currently in the print buffer and also to write them to disk.

For more information, see:
Print View window on page E-70
Media Write window on page E-74

Rack Archival Report

```
                                  Rack Archival Report                02/12/08      13:19

TRAY POS. : 1          ARCHIVE DATE : 01/12/08 12:05 - 02/12/08 12:35
OPERATOR ID : admin
INSTRUMENT NAME : cobas 6000                                  INSTRUMENT ID : 1

R.NO.        S.NO.                 ID             S.TYPE     COMMENT
 00189-1     000026                               Ser/Pl
 00189-2     000027                               Ser/Pl
 00189-3
 00189-4
 00189-5
 00480-1     000021                               Ser/Pl
 00480-2     000022                               Ser/Pl
 00480-3     000023                               Ser/Pl
 00480-4     000024                               Ser/Pl
 00480-5     000025                               Ser/Pl
E00009-1     000005                               Ser/Pl
E00009-2     000006                               Ser/Pl
E00009-3
```

Figure E-117 Rack Archival Report

Rack Archival Report explanation

The **Rack Archival Report** lists archived racks.

Date, Time The date and time the report was printed appears to the right of the report name.

TRAY POS. This field displays the tray position.

ARCHIVE DATE This field displays the range of date and time covered by the report.

OPERATOR ID This field displays the identification of the operator logged onto the system when the report was printed.

INSTRUMENT NAME This field displays the name of the instrument.

INSTRUMENT ID This field displays the ID number of the instrument.

R.NO. This column displays the rack number and position of the sample.

S.NO. This column displays the sequence number of the sample.

ID This column displays the sample ID.

S.TYPE This column displays the sample material type.

COMMENT This field displays the text entered in the **Main Comment** field (for example Name) on the **Demographics** windows.

For more information, see:
Comment Title window on page E-383
Demographics window on page E-211

Pressure Sensor Voltage Adjust

➔ **Print** (global button) > **Utility** > **Pressure Sensor Voltage Adjust**

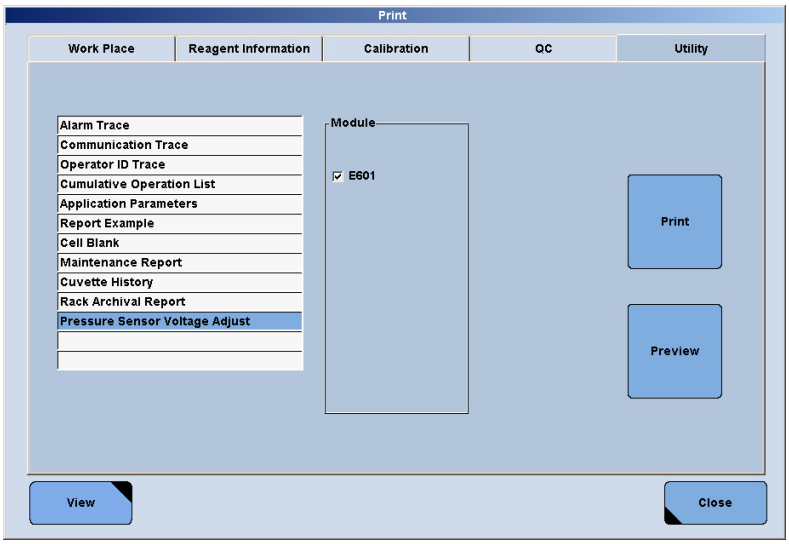


Figure E-118 Pressure Sensor Voltage Adjust print screen

Module Select the check box for the desired module.

For information on the tabs, see *Print screen* on page E-68.

Buttons

Print Choose this button to send the selected report to the printer and to store it in the print buffer.

Preview Choose **Preview** and then **View** to display a preview of the currently selected report without printing the report.

View Choose this button to view the lists and reports currently in the print buffer and also to write them to disk.

For more information, see:
Print View window on page E-70
Media Write window on page E-74

Reports Printed from Utility > Maintenance

The reports discussed in this section are automatically displayed on the **Print View** window upon completion of the selected maintenance check.

See *Print View window* on page E-70.

Hard Disk Check report

The **Hard Disk Check** report can be printed upon completion of the **Check Disk** maintenance function. Choose **Utility** > **Maintenance** > **Check** (**Maintenance Type**) and select **Check Disk** from the **Maintenance** Items list. Then choose **Select** to display the **Check Disk** window. Choose the **Hard Disk Drive** option from the **Media** area select program and **Data** and **Extension**, and then choose **Execute** to start the **Check Disk** function.

```
                                    Hard Disk Check (Core)                 04/12/08   18:58

     DIRECTORY    /sd0a/

FILE NO.          FILE NAME                                  SIZE      DATE          TIME
        1         F_Physic.csv                               1717   27/11/08        15:44
        2         F_Struct.csv                              37253   27/11/08        15:44
        3         ISA11                                    659724   27/11/08        15:44
        4         ISA16                                    187542   27/11/08        15:44
      ...

CHECK SUM

                  FILE NAME                          SUM
                  F_Physic.csv                      D419
                  F_Struct.csv                      A065
                  ISA11                             4F5F
                  ISA16                             9215
      ...

TOTAL FILES:                          27 FILE(S)
TOTAL SIZE:                    22695775 BYTE(S)
TOTAL SUM:                         3627

SYSTEM PROGRAM VERSION:  7277112-03-01

                          Hard Disk Check (Control Unit)                   04/12/08   18:59

     DIRECTORY c:\c2000exe\exe\opt\

FILE NO.          FILE NAME                                  SIZE      DATE          TIME
        1         AlarmMDB.dll                              32768   29/06/06        23:28
        2         AppTest.exe                               77824   22/09/05        13:54
      ...

                          Hard Disk Check (Control Unit)                   04/12/08   18:59

     DIRECTORY c:\c2000exe\exe\uni\

FILE NO.          FILE NAME                                  SIZE      DATE          TIME
        1         AlarmMDB.dll                              32768   19/09/06        16:20
        2         CommonDBRes.exe                           28672   28/07/06        22:59
      ...


TOTAL FILES:                         343 FILE(S)
TOTAL SIZE:                  892105016 BYTE(S)
TOTAL SUM:                       435d

SYSTEM PROGRAM VERSION:  7277112-03-01
```

Figure E-119 Hard Disk Check report

Hard Disk Check report explanation

The **Hard Disk Check** report lists the contents of the database, the system program version, and the check sum of the instrument RAM and ROM for both the core and control unit databases.

Date, Time	The date and time the report was printed appears to the right of the report name.
FILE NO.	This column displays the sequential number given to the files on the database by the system.
FILE NAME	This column displays the file name.
SIZE	This column displays the size (Bytes) of the file.
DATE	This column displays the date the file was last updated.
TIME	This column displays the time the file was last updated.
TOTAL FILES	This field displays the total number of files found on the database.
TOTAL SIZE	This field displays the total size (Bytes) of all the files found on the database.
SYSTEM PROGRAM VERSION	This field displays the software version installed.
CHECK SUM	This area displays the check sums of each of the files. The file name is displayed followed by the check sum.
TOTAL SUM	This field displays the total sum of the files.

Backup Disk report

The **Backup Disk** report can be printed upon completion of the **Check Disk** maintenance function. Choose **Utility** > **Maintenance** > **Check** (**Maintenance Type**) and select **Check Disk** from the **Maintenance** Items list. Then choose **Select** to display the **Check Disk** window. Choose the **Floppy Disk** option from the **Media** area, and then choose **Execute** to start the **Backup Disk** report function.

```
                          Backup Disk Report                  04/12/08     18:55

DIRECTORY A:\*.*

   FILE NO.     FILE NAME               SIZE          DATE          TIME
         1      1DMBCD.txt                830       28/05/08       16:16
         2      2DMRepor.txt             1784       28/05/08       17:15
         3      3DMNoBC.txt               786       29/05/08       08:32
         4      4RepNoBC.txt             2068       29/05/08       08:32
         5      5RM1+2.txt               3644       29/05/08       17:42
         6      6RM1-2.txt               2044       29/05/08       17:41
         7      gluccali.txt              622       20/02/07       09:09
         8      glucreac.txt              895       20/02/07       09:05


TOTAL FILES:               8  FILE(S)
TOTAL SIZE:            12673  BYTE(S)
```

Figure E-120 Backup Disk report

Backup Disk report explanation

The **Backup Disk** report lists the contents of the floppy disk.

Date, Time The date and time the report was printed appears to the right of the report name.

DIRECTORY This field displays the directory name, if applicable.

FILE NO. This column displays the sequential number given to the files on the floppy disk by the system.

FILE NAME This column displays the file name.

SIZE This column displays the size (Bytes) of the file.

DATE This column displays the date the file was last updated.

TIME This column displays the time the file was last updated.

ISE Check report

The **ISE Check** report is printed upon completion of the **ISE Check** maintenance function. Choose **Utility** > **Maintenance** > **Check** (**Maintenance Type**) and select **ISE Check** from the **Maintenance** Items list. Then choose **Select** to display the **ISE Check** window. Select the module and enter the number of cycles. Add comments if appropriate. Choose **Execute** to start the **ISE Check** function.

The **ISE Check** report shows the electromotive force (mV) values of the internal standard solution.

ISE Check 04/12/08 19:25

MODULE C

NO.	NA EMF	K EMF	CL EMF	KCL EMF	IS
1	-39.9	-46.8	133.2	-0.1	IS2
2	-39.9	-46.8	133.2	-0.1	IS2
3	-39.9	-46.8	133.2	-0.1	IS2
4	-39.9	-46.8	133.2	-0.1	IS2
5	-39.9	-46.8	133.2	0.0	IS2
6	-39.9	-46.8	133.3	0.0	IS2
7	-39.9	-46.8	133.3	0.0	IS2
8	-39.9	-46.9	133.3	0.1	IS2
9	-40.0	-46.9	133.3	0.0	IS2
10	-39.9	-46.8	133.2	0.0	IS2

Figure E-121 ISE Check report

ISE Check report explanation

Date, Time The date and time the report was printed appears to the right of the report name.

NO. This column displays the number of replicate measurement of internal standard performed during the ISE Check.

NA EMF This column displays the electromotive force (mV) values of the sodium electrode for each ISE check performed. The number should fall within the range of -90 to -10 mV.

K EMF This column displays the electromotive force (mV) values of the potassium electrode for each ISE check performed. The number should fall within the range of -90 to -10 mV.

Cl EMF This column displays the electromotive force (mV) values of the chloride electrode for each ISE check performed. The number should fall within the range of 80 to 160 mV.

KCL EMF This column displays the electromotive force (mV) values of the reference electrode for each ISE check performed. The number should fall within the range of -7 to 7 mV.

Within 30 cycles the difference from measurement to measurement should be within 0.2 mV. Over the total cycle range the difference should not exceed 2 mV.

IS This column displays the position (IS1 or IS2) of the ISE IS bottle.

Barcode Reader Check report

There are 2 versions of the **Barcode Reader Check** report: **Sample Barcode Reader Check** and **Reagent Barcode Reader Check**. The **Barcode Reader Check** report lists the barcode numbers read by each of the barcode readers on the system.

The **Barcode Reader Check** reports can be printed upon completion of the **Barcode Check** maintenance check function. Select the **Barcode Check** function from **Utility** > **Maintenance** and choose **Select**. The **Barcode Check** window is displayed. Select the **Sample Barcode** option in the **Item** area to run the check and a report for only rack and sample barcode readers.

Sample Barcode Reader Check report

```
                        Sample Barcode Reader Check      04/12/08     19:41

MODULE    Sample Line
RACK           POS.1                POS.2              POS.3
               POS.4                POS.5
00037                  000912                500201             500125
                       000148                000105
00037                  000912                500201             500125
                       000148                000105
00037                  000912                500201             500125
                       000148                000105
00037                  000912                500201             500125
                       000148                000105
00037                  000912                500201             500125
                       000148                000105
```

Figure E-122 Sample Barcode Reader Check report

Sample Barcode Reader Check report explanation

Date, Time The date and time the report was printed appears to the right of the report name.

RACK This column identifies the rack number read from the 4 binary strips on the rack.

POS. NO./POS.1 to POS.5 This column identifies the barcode number read for each position in the rack. Positions that do not contain samples are displayed with an asterisk followed by 22 dashes.

Reagent Barcode Reader Check report

Select the **Reagent Barcode** option in the item area to check the reagent barcode reader. If **Reagent Barcode** is selected, specify the number of reagent disk positions to be checked in the **Cycles** text box.

```
                    Reagent Barcode Reader Check                 05/12/08      16:44

MODULE        C
NO.         RESULT                          NO.         RESULT
1           03685616950480809000216100      2           03685616950480809000216100
3           03685616950480809000216100      4           03685616950480809000216100
5           03685616950480809000216100

            OK      NG
TOTAL       5       0
```

Figure E-123 Reagent Barcode Reader Check report **c** 501 module

```
                          Reagent Barcode Reader Check           05/12/08       16:45

MODULE e2
POS.    RESULT  POS.    RESULT  POS.    RESULT  POS.    RESULT  POS.    RESULT
1       --      8       --      15      OK      22      OK      4       --
11      OK      18      OK      25      OK      7       OK      14      --
```

Figure E-124 Reagent Barcode Reader Check report **e** 601 module

Reagent Barcode Reader Check report explanation

Date, Time The date and time the report was printed appears to the right of the report name.

MODULE This field displays the name of the module on which the check is performed.

POS. These columns display the position number for the reagent disk that was checked.

RESULT These columns display the result of the barcode reader check of the corresponding position. OK indicates no problems arose and -- indicates that nothing was detected in that position.

Start Conditions screen

➔ **Start** (global button) or press the <F2> key

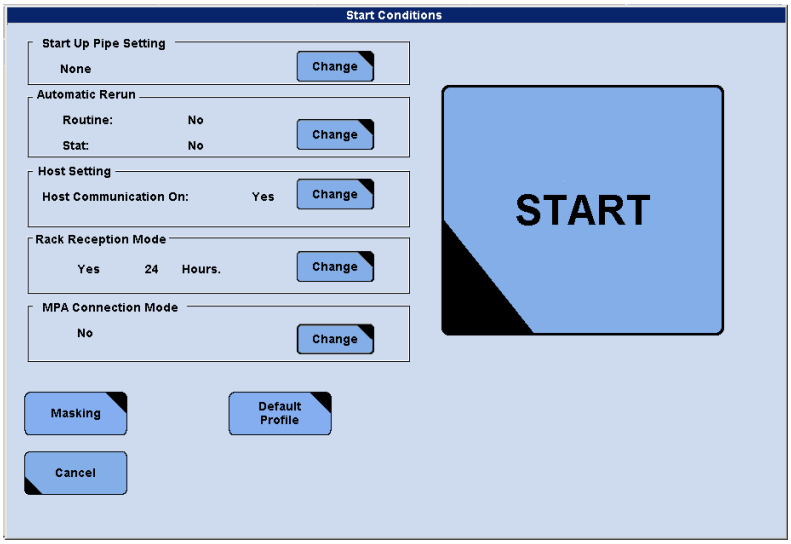


Figure E-125 Start Conditions screen (barcode mode)

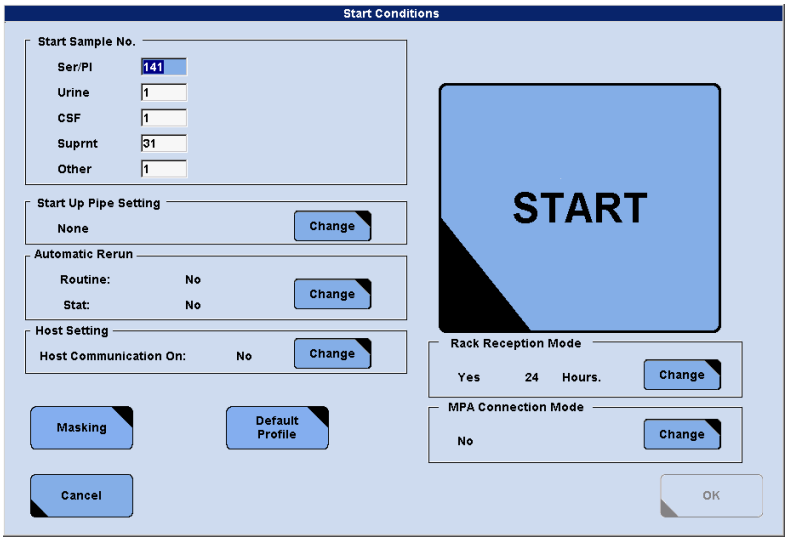


Figure E-126 Start Conditions screen (non-barcode mode)

Use this screen to start a measurement and to define or request operating parameters such as **Start Up Pipe Setting**, **Automatic Rerun**, **Host Communication**, **Rack Reception Mode**, **Masking**, and **Default Profile**.

👁 For more information on each of these items, see:
Start Up Pipe Setting area on page E-187
Automatic Rerun area on page E-188
Host Setting area on page E-188
Rack Reception Mode area on page E-189
Masking on page E-189
Default Profile on page E-189

For detailed operation procedures, see:
To start processing on page B-64
Requesting calibration and QC and printing load lists on page B-52

Start Sample No. area (non-barcode mode)

Use this area to enter the start sample number for each sample type. The database holds up to 10,000 sample records, which can be numbered from 1 to 60,000.

Once the database is full, no more sample data can be saved. In the **System Overview** screen the **Sample Data Clear** button turns to red. To save further data, the database must be cleared.

It is recommended to backup and delete data daily.

Ser/Pl Use this text box to enter the start sample number for **Ser/Pl** samples.

Urine Use this text box to enter the start sample number for **Urine** samples.

CSF Use this text box to enter the start sample number for **CSF** samples.

Suprnt Use this text box to enter the start sample number for **Suprnt** samples.

Other Use this text box to enter the start sample number for **Other** samples.

Start Up Pipe Setting area

This area displays the currently selected start up pipe name. If no start up pipe is selected, **None** is displayed in the **Start Up Pipe Setting** area.

Pipe functions are defined on **Utility** > **System** (**Page 2/4**) > **Pipe Setting**.

See *Maintenance Pipe Setting window* on page E-397.

No green wash rack during Start Up Pipe

The green wash rack procedure will not be performed during the Start Up Pipe, even though it is defined in the corresponding pipe settings.

Once the start up pipe begins, the setting is reset to **None**.

Change Choose this button to select the desired start up pipe from the list box.

See *Pipe Function window* on page E-190.

Automatic Rerun area

This area displays whether routine and/or STAT samples have been selected for automatic rerun. If **Routine** or **STAT** is selected **Yes** is displayed. No indicates the function is disabled.

Automatic rerun setting has to be done *application-specific* and *system-wide*.

In addition to the application-specific setting, there is a system-wide setting for the automatic rerun function. It is displayed in the **Automatic Rerun** area on the **Start Conditions** window.

Automatic rerun setting has to be done *application-specific* and *system-wide*.

- The application-specific setting needs to be configured only once during installation of a new application.
- The system-wide setting is done on **Automatic Rerun** window.

For more information on automatic rerun processing, see *Processing reruns* on page B-67.

Change Choose this button to display the **Automatic Rerun** window.

See *Automatic Rerun window* on page E-191.

Host Setting area

This area displays if Host communication is enabled. If enabled, **Yes** is displayed, if **No** is displayed the function is disabled.

The Host communication settings are defined on the **Utility** > **System** (Page 1/4) > **Host Communication Setting** window.

See *Host Communication Setting window* on page E-376.

The different host communication settings need to be configured only once during installation.

The host communication has to be activated on the **Host Setting** window.

Change Choose this button to enable or disable Host communication.

See *Host Setting window* on page E-192.

Rack Reception Mode area

The rack reception mode must be activated and configured on the **Rack Delivery** window under **Utility** > **System** (**Page 3/4**). If it is activated, you can enable or disable the rack reception mode for the upcoming analysis here.

If ***Yes*** is displayed in the **Rack Reception Mode** area, the mode is used in the upcoming analysis. If **No** is displayed, the mode is inactive.

For information on how to change the system settings for the rack reception mode, see *Rack Reception Mode* on page E-413.

The **Rack Reception Mode** area is not displayed if the **MPA Connection Mode** is activated.

Change Choose this button to clear or select the check box in the **Rack Reception Mode** window.

If you deselect the **Rack Reception Mode**, then the instrument will perform the finalization and turn into standby after all samples are processed, no matter how much longer the rack reception time would be.

See *Rack Reception Mode window* on page E-193.

MPA Connection Mode area

This area is displayed when the connection to a **MODULAR** *PRE-ANALYTICS* (MPA) is enabled. If enabled, **Yes** is displayed. If **No** is displayed, the function is disabled.

Change Choose the **Change** button to temporarily disable the connection to the **MODULAR** *PRE-ANALYTICS*.

See *MPA Connection Mode window* on page E-194.

Buttons

This section describes the buttons of the **Start Conditions** screen.

Start Use this button to start an analysis run.

The analyzer performs preparation routine and then begins to process the samples.

See *Starting the measurement* on page B-64.

Masking Use this button to manually mask/unmask tests and modules.

See *Masking window* on page E-195.

Default Profile Use this button to define the profile and sample types to be used as the default if no test selections are made for a sample.

See *Default Profile Per Sample Type window* on page E-198.

OK Choose **OK** to accept the change.

Cancel Choose **Cancel** to close the window without saving any changes.

Pipe Function window

➔ **Start** (global button) > **Change** (**Start Up Pipe Setting** area)

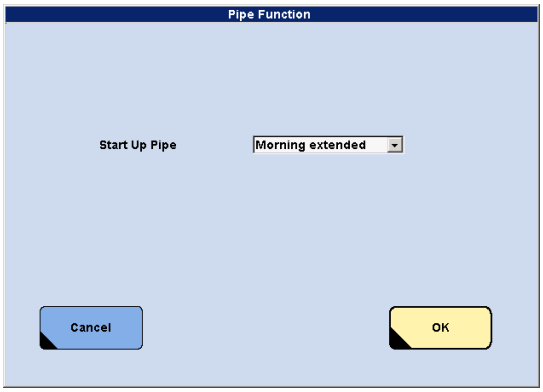


Figure E-127 Pipe Function window

Use this window to select the desired **Start Up Pipe** from the list box. The maintenance items included in the selected **Start Up Pipe** will be executed automatically before start of analysis.

No green wash rack during Start Up Pipe

The green wash rack procedure will not be performed during the Start Up Pipe, even though it is defined in the corresponding pipe settings.

OK Choose **OK** to accept the change.

Cancel Choose **Cancel** to close the window without saving any changes.

No Pipes are displayed, if no maintenance pipe has been defined. At least one maintenance pipe must have been defined on the **Utility** > **System** (**Page 2/4**) > **Pipe Setting** screen first.

For more information about maintenance pipes, see *Maintenance Pipe Setting window* on page E-397.

Automatic Rerun window

➔ **Start** (global button) > **Change** (**Automatic Rerun** area)

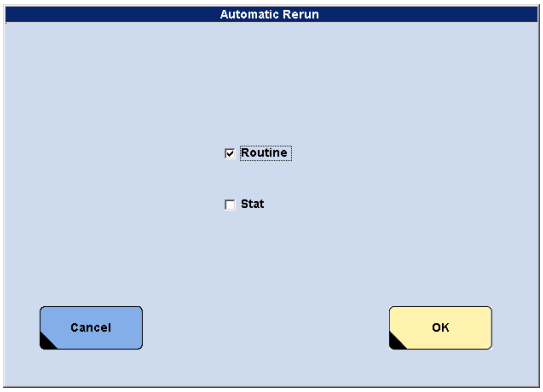


Figure E-128 Automatic Rerun window

Use this window to select or deselect **Routine** and/or **STAT** samples for automatic rerun. Select the corresponding check box.

OK Choose **OK** to accept the change.

Cancel Choose **Cancel** to close the window without any changes.

Host Setting window

➔ **Start** (global button) > **Change** (**Host Setting** area)

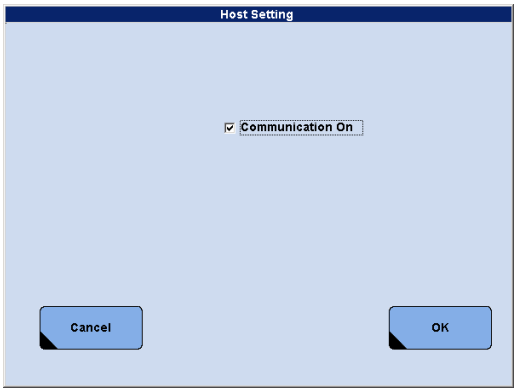


Figure E-129 Host Setting window

Use this window to enable or disable Host communication. Select the **Communication On** check box to enable Host communication.

OK Choose **OK** to accept the change.

Cancel Choose **Cancel** to close the window without any changes.

Rack Reception Mode window

➔ **Start** (global button) > **Change** (**Rack Reception Mode** area)

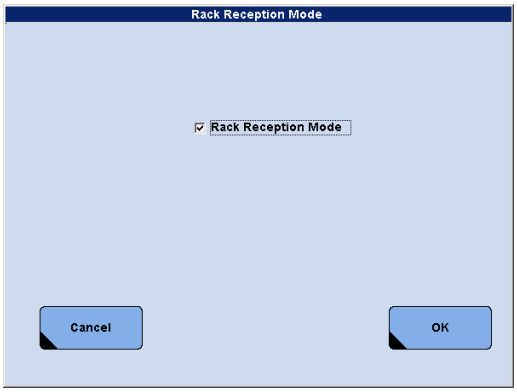


Figure E-130 Rack Reception Mode window

Use this window to select or deselect the **Rack Reception Mode** for the upcoming analysis.

Rack Reception Mode

If you deselect the **Rack Reception Mode** check box, then the instrument will perform the finalization and turn into standby after all samples are processed, no matter how much longer the rack reception time would be.

The rack reception mode must have been activated and configured on the **Rack Delivery** window under **Utility** > **System** (**Page 3/4**). In this case, you can enable or disable the rack reception mode for the upcoming analysis here.

For information on how to change the system settings for the rack reception mode, see *Rack Reception Mode* on page E-413.

OK

Choose **OK** to accept the change.

Cancel

Choose **Cancel** to close the window without any changes.

MPA Connection Mode window

➔ **Start** (global button) > **Change** (**MPA Connection Mode** area)

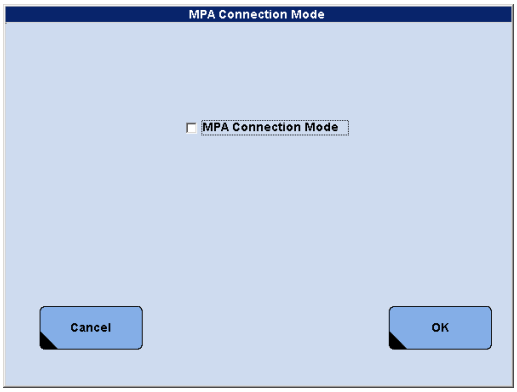


Figure E-131 MPA Connection Mode window

Use this window to enable or disable the MPA connection.

MPA Connection Mode Select the **MPA Connection Mode** check box to enable the connection to the **MODULAR** *PRE-ANALYTICS*.

Deselect the **MPA Connection Mode** check box to temporarily disable the connection to the **MODULAR** *PRE-ANALYTICS*.

OK Choose **OK** to accept the change.

Cancel Choose **Cancel** to close the window without any changes.

Masking window

➔ **Start** (global button) > **Masking**

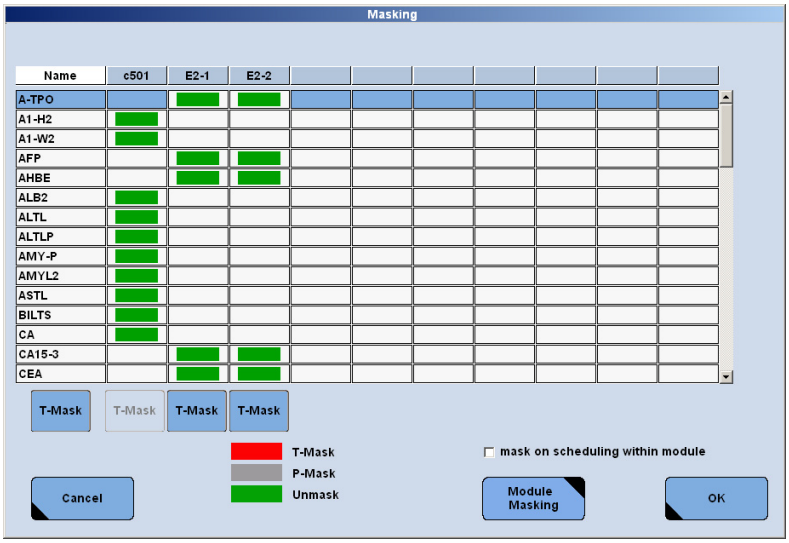


Figure E-132 Masking window

Use this window to manually **T-mask** (Test mask), **P-mask** (Patient mask) or **unmask** tests and to access the **Module Masking** window.

Masking list

This list displays all tests that are assigned to each module. It can be sorted by test (by choosing the **Name** tab) or module (by choosing the module tab).

If any module is masked from the **Module Masking** window, the module column of the test list appears yellow.

Red – test is masked for any kind of sample (T-mask)

Gray – test is masked only for patient samples (P-mask)

Green – test is unmasked

T-Mask/P-Mask/Unmask

Use these buttons to T-mask, P-mask, or unmask the selected test(s). Select a test(s) and then choose the **T-Mask/P-Mask/Unmask** button. Any number of tests can be masked. Tests can be masked completely, or just for individual modules and channels. There are two possibilities to mask a test. If **T-mask** is selected, neither patient samples nor controls or calibrations can be performed. If **P-mask** is selected, the test is masked for patient samples only—calibration and QC can be performed.

The system does not need to be in standby to mask or unmask a test.

*Mask on scheduling within module (**e** 601)*

Allows to re-schedule the tests to the other channel.

All scheduled tests are redirected to the other measuring channel of the same module, if the test is assigned to both. Tests are not re-scheduled to a second module.

Module Masking

Choose the **Module Masking** button to display the **Module Masking** window. Use this window to mask an individual module to perform maintenance on the masked module while the other modules are still processing samples.

See *Module Masking window* on page E-197.

Module Masking window

➔ **Start** (global button) > **Masking** > **Module Masking**

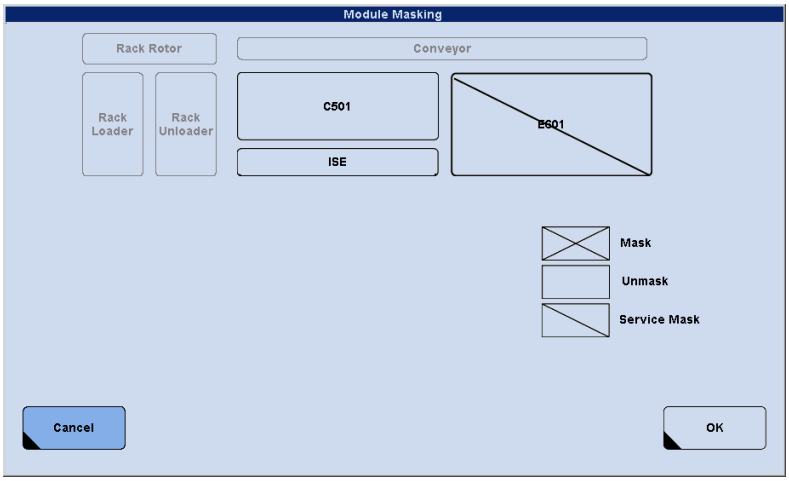


Figure E-133 Module Masking window

Use this window to mask an individual module to perform maintenance on the masked module while the other modules are still processing samples. If any module is masked on the **Module Masking** window, the **Module** column of the test list on the **Masking** window appears yellow.

For detailed instructions, see *Performing background maintenance* on page C-36.

Module button Choosing the module button toggles between the masking statuses.

- **Mask** – Module Mask; used when performing background or parallel maintenance
- **Unmask** – normal operation, no masking is activated
- **Service Mask** – used if your Roche service representative has to perform service actions for example checks via service software

The module can be masked/unmasked when the system is either in standby or operation.

Default Profile Per Sample Type window

➔ **Start** (global button) > **Default Profile**

This screen can be accessed by an operator with administrator level password only.

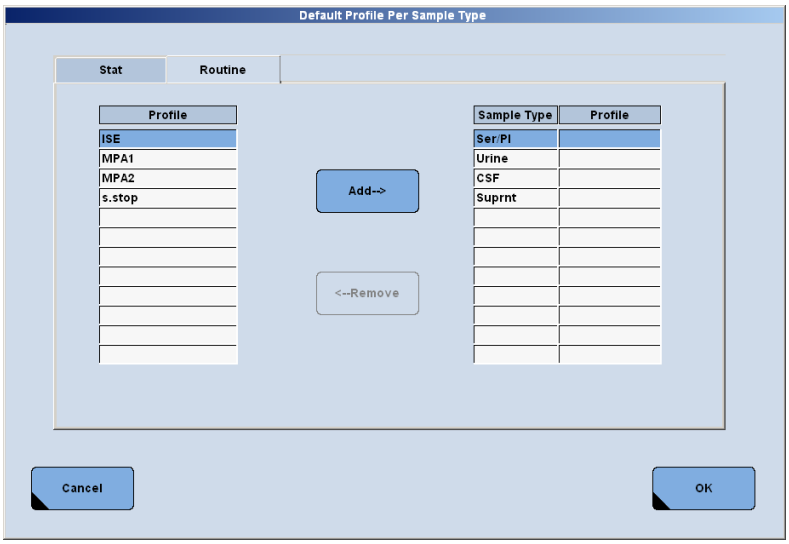


Figure E-134 Default Profile Per Sample Type window

Use this window to define the profile for a sample type to be used as the default if no test selections are made for a sample.

Profiles are defined on **Utility** > **System** (**Page 1/4**) > **Key Setting** > **Profile Setting**.

STAT / Routine Default profiles are defined separately for STAT and routine samples. Choose the **Stat** or **Routine** tabs to display the desired window.

Profile List This list displays all profiles defined on the system for the selected sample (**STAT** or **routine**). Use this list to select the profile that is to be added to the sample type as the default. Only one profile can be assigned per sample type.

Sample Type/Profile List This list displays the available sample types and the currently assigned default profile. Use this list to select the sample type to be added to the profile as the default. If a profile is already assigned, it is displayed next to the sample type. Only one profile can be assigned per sample type.

Buttons

Add--> Use this button to add the selected profile to the selected sample type.

Select the sample type in the **Sample Type/Profile** list. Then select the profile name in the **Profile** list. Choose the **Add** button to add the profile to the selected sample type as the default profile.

<--Remove Use this button to remove a profile assigned to a sample type.

Select the sample type to be changed and choose **Remove**. The associated profile is removed and reappears in the **Profile** list.



The **OK** button turns yellow when any changes are made. Choose the **OK** button to save the changes.

Confirmation window

Use the buttons on the **Confirmation** window to continue with the action or to stop the action.

Yes/OK/Execute Choose **Yes**, **OK**, or **Execute** to start or complete the action.

No/Cancel/Close Choose **No**, **Cancel**, or **Close** to stop or cancel the action.

No Help available

For this topic there is no Help available.

No Help available

Workplace menu

Use the **Workplace** menu to make test selections, specify patient demographics, assign patient ID numbers and position numbers to samples, as well as review, backup, edit, delete and send data to the Host.

In this chapter *Chapter* 23

Test Selection screen E-203
Sample area E-204
Fields E-204
Test matrix E-208
Colors E-208
Markings E-209
Buttons E-210
Demographics window E-211
Sample Information E-211
Patient Information E-212
Barcode Read Error window (barcode mode) E-213
Buttons E-213
Rerun Rack Assignment window (non-barcode mode) E-214
Fields E-214
Button E-214
Repeat Test Selection window (non-barcode mode) E-215
Data Review screen E-216
Filter area E-217
Data list box E-217
Fields E-217
Sample selection list E-218
Test results list E-219
Buttons E-220
Read Backup Disk window E-222
Media area E-222
Search Sample window E-223
Find area E-224
Search Option area E-224
Search area E-224
Filter window E-225

Send To Host window E-227
Data Type area E-227
Test Host Status area E-227
Run Type area E-228
Fields E-228
Button E-228
Delete All window E-229
Backup Data window E-230
Media area E-230
File Format area E-231
Button E-231
Test Review window E-232
Test Review window for patient samples E-232
Sample Data area E-232
Test result list E-233
Test Review window for QC samples E-235
Sample Data area E-235
Test result list E-236
Buttons E-237
Detail window E-238
Manual Test window E-239
Reaction Monitor window E-240
Reaction information E-241
Graph area E-241
Buttons E-241
Scale Setting window E-242
Overlay window E-243
Buttons E-244
Calib. Review screen E-245
Calibrator selection list E-246
Test results list E-247
Buttons E-247

Test Selection screen

➔ **Workplace > Test Selection**

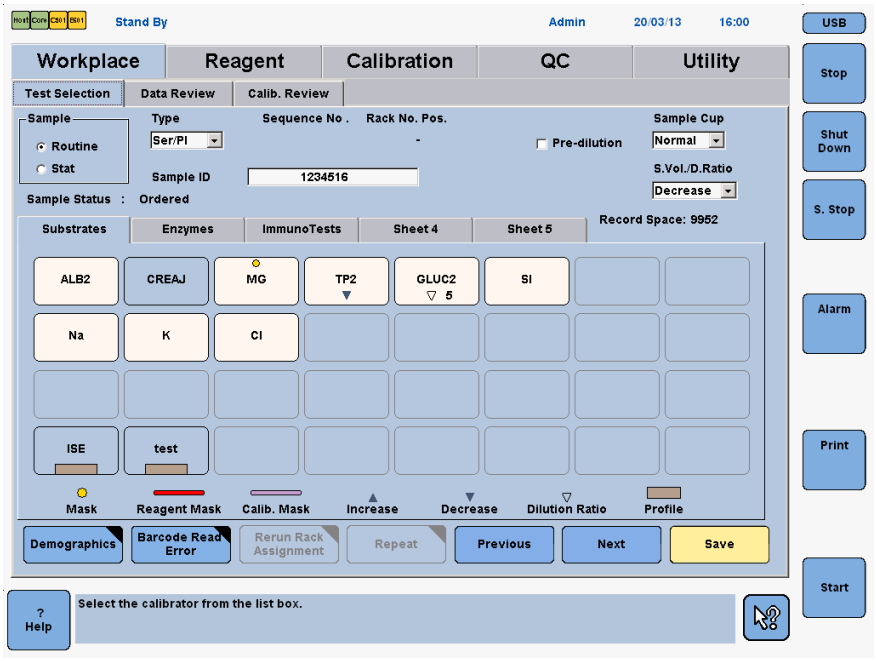


Figure E-135 Test Selection screen (barcode mode)

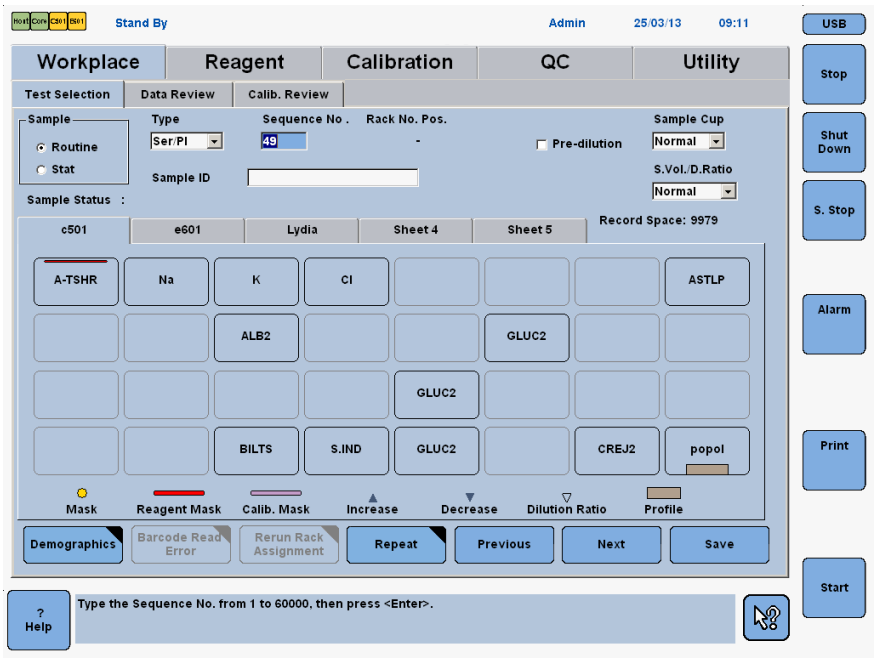


Figure E-136 Test Selection screen (non-barcode mode)

Use the **Test Selection** screen to enter test selections and demographics for a sample.

The available fields vary, depending on whether STAT or routine test selections are being entered and whether the system is operating in barcode mode or non-barcode mode.

See *Requesting a test manually* on page B-83.

Sample area

Use this area to select the sample priority for which details are to be entered (**STAT** or **Routine**). This function is available both in barcode and non-barcode mode.

Routine Select the **Routine** option to enter test selections for a routine sample.

See *To request a routine sample* on page B-84.

STAT Select the **STAT** option to enter test selections for a STAT sample.

See *To request a STAT sample* on page B-85.

Fields



All manual selections such as sample type and dilution ratio remain as selected, within and between samples, until they are manually reset.

Type Use this list box to select the sample type:

- **Ser/Pl**: Use this sample type for serum or plasma.
- **Urine**: Use this sample type for urine samples.
- **CSF**: Use this sample type for cerebrospinal fluids.
- **Suprnt**: Use this sample type for supernatants or for whole blood on **c** 501 module.
- **Other**: Use this sample type for other body fluids than mentioned above.

This selection changes the test matrix, that is, the test matrix displays the available tests for the selected sample type.

Sequence No. (non-barcode mode) Use this text box to enter the sequence number. The sequence number is used by the system to associate test selections to a sample when the system is operating in non-barcode mode. This function is only available when **Routine** is selected in the **Sample** area.

Type a sequence number in the text box (1 to 60000) and press <Enter>. The cursor moves to **Sample ID**.



In non-barcode mode, a sequence number is not required for STAT samples.

Rack No.-Pos. (non-barcode mode)

Use these text boxes to enter the rack number and the position of the sample tube in the rack for STAT samples. Type the rack number in the first text box and press <Enter>. This function is only available when **STAT** is selected in the **Sample** area.

Type the position number (1 to 5) corresponding to the sample position in the rack and press <Enter>. The cursor moves to **Sample ID**.

See *Sample racks* on page A-59.

Sample ID

Use this text box to define a sample identification of up to 22 characters and press <Enter>. The cursor moves to **Pre-dilution**.

If the system is connected to a Host, this information is downloaded automatically and no entry is necessary.

Pre-dilution

Select this check box if the sample has been manually diluted and press <Enter>. The cursor moves to **Sample Cup**. On the print out and when sending the result to Host, the results are flagged with a P.

Samples which have been manually prediluted can be measured, but the corresponding dilution factors are NOT taken into consideration when the results are calculated by the analyzer. It is the operator's responsibility to calculate the final results.

Sample Cup

Use this list box to define the sample cup type, **Normal** or **Micro**, used for the current sample. Select the appropriate sample cup type from the list and press <Enter>. The cursor moves to **Sample Volume/Dilution**.

For more information about sample cups, see *Sample containers* on page A-61.

Restrictions for the use of micro cups

When the end of sample probe touches the inner wall of a micro cup this may result in improper sample aspiration.

- Do not use micro cups on **e** 601 modules.
- Do not use micro cups for calibrators and controls.

S. Vol./D.Ratio Use this list box to select the concentration for the current sample (**Normal**, **Decrease**, or **Increase**) or the required dilution.

To apply sample volume or dilution to a test, first select the required volume/dilution, and then select the test. If a sample is analyzed with several tests, a different volume or dilution can be defined for each test performed.

The volumes for **Normal**, **Decrease** and **Increase** are defined on **Utility** > **Application** > **Analyze** for **c** 501. When you choose **Decrease** for **e** 601 it refers to dilution ratio in the **For Rerun** list box in the **Default Dilution Ratio** area in **Utility** > **Application** > **Analyze**. The **e** 601 cannot pipette increased sample volume.

When you choose **Normal** for **e** 601 it refers to dilution ratio in the **For 1st** list box in the **Default Dilution Ratio** area in **Utility** > **Application** > **Analyze**.

Priority of dilution requests:

1. Selection in the **S.Vol./D.Ration** list box on the **Test Selection** screen or request by the host. If both the operator and the host enter or send a ratio the last one is performed.
2. Pre-programmed dilution ratio indicated in the **Utility** > **Application** > **Analyze** screen.

For more information, see:
Sample Volume area on page E-487
Default Dilution Ratio area on page E-493

- Application-specific dilutions are performed automatically by the analyzer.
- Not all displayed dilution ratios are available for every test.
- If you choose **Normal** in the **S. Vol./D.Ratio** field the predefined dilution is used.
- If you choose **1:1** in the **S. Vol./D.Ratio** field no dilution at all is performed.
- ISE: Test dilution is not available. Only for a manual rerun of a urine sample **Decrease** (6.5 µL) is available.
- If you choose a dilution ratio in the **S. Vol./D.Ratio** field, this selection will overwrite the pre-programmed dilution ratio indicated in the **Utility** > **Application** > **Analyze** screen. If for example the test has a pre-programmed dilution ratio (normal) of 1:5 and you select a dilution ratio of 1:2 for **S. Vol./D.Ratio**, the test is processed with a dilution of 1:2.
- A manually programmed dilution ratio might be overwritten by the host order.
- **c** 501: If the sample volume of a test is higher than 20 µL, a manually programmed dilution is not accepted and a pop-up window is displayed.
- **c** 501: HbA1c (whole blood) tests, only 1:10, 1:20, and 1:50 are possible to order.
- **e** 601: Applications are not specified for increased sample volume.
- **e** 601: The recommended dilutions are given in the instructions for use for the individual test.

Sample Status This field displays the status of the selected sample. Possible statuses include:

Ordered	Sample registered by user or Host or some requests cannot be performed if for example the reagent is masked.
Processing	Sample ID or rack ID has been read by core.
Incomplete	Samples processed, but a data alarm is present.
Complete	Samples successfully processed.
Sent to Host	Sample results have been sent to the Host.

Record Space This field displays the number of available records for patient programming. 10,000 STAT and routine patient records can be stored in the database (**Routine View**).

Test matrix

The test matrix displays test keys that are assigned to single tests or to test profiles. Choose a test key to request the corresponding test or test profile. After choosing all required tests and/or test profiles, choose **Save** to save your request.

The test keys are ordered in 5 groups. Use the tabs above the test matrix to switch between the groups. The available test keys vary, depending on the sample type.

Group names and test keys are defined on **Utility** > **System** (**Page 1/4**) > **Key Setting**.

For more information, see:
Key Setting window on page E-384
To define a group name on page B-281

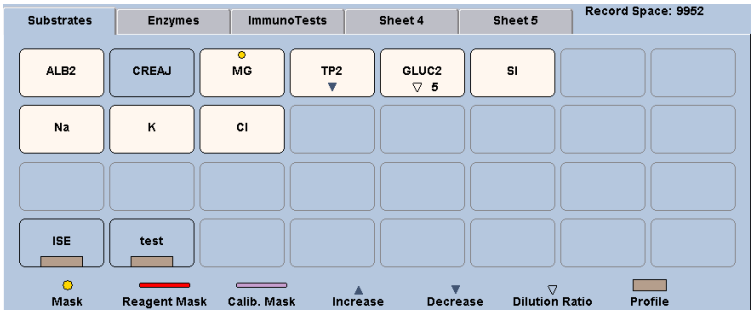


Figure E-137 Test matrix

Colors

The test keys display different colors to indicate the status of the test for the sample ID in the **Sample ID** text box. The following colors are available:

This test has been selected.

This test has been performed, a result is available, and can be reordered again.

A rerun has been performed for this test and the result is available.

Markings

One test or profile can be assigned to each key. The test keys display special markings depending on the test's status or programming. The different markings and their meanings are outlined below:



Blank test key indicates no test is assigned.



Test key with a test or profile name and no masking indicators can be requested, further settings are not required. The reagent is on board and registered.



Mask

- Test manually masked on the **Masking** window (**Start** (global button) > **Masking**, **P**- or **T**-**mask** on all measuring cells for **e** 601)
- All modules which have this test on board are deactivated

The test can be requested. However, the test is performed only after the test is manually unmasked

Reagent Mask (no reagent available)

Test is automatically masked by the system. The volume of a reagent (**cobas c** pack or **cobas e** pack), or detergent cassette, that is required for the respective test is either insufficient or the reagent is not present on the analyzer. The test can be requested.

c 501: If a diluent **cobas c** pack or other wash solutions are empty or missing (Sample Cleaner 1, Sample Cleaner 2, or ProbeWash), the corresponding reagent is **not** masked.

e 601: If the necessary diluent or pretreatment are empty or missing, the corresponding test is masked.

Calib. Mask (calibration failed)

Test is automatically masked by the system due to a failed or missing calibration.

The purple bar will not be displayed on the test key if:

- Calibration auto masking setting for the individual test is not selected on **Utility** > **Application** > **Calib**.
- Calibration auto masking setting for the analyzer is not selected on **Utility** > **System** (**Page 2/4**) > **Calib Mask Setting**.



Increase (**c** 501)

Test will run with an increased sample concentration as set on the **Utility** > **Application** > **Analyze** screen.

The symbol disappears as soon as the result is generated.



Decrease

Test will run with a decreased sample concentration as set on the **Utility** > **Application** > **Analyze** screen.

The symbol disappears as soon as the result is generated.



Dilution Ratio

Test will run with a dilution. The number after the triangle indicates the dilution factor (for example, 2 indicates a 1:2 dilution).

The symbol disappears as soon as the result is generated.



Profile

A brown bar on the key indicates the key has been assigned a profile. When selected, all tests assigned to that profile are highlighted.

Buttons

Demographics Choose this button to display the **Demographics** window. Use this window to enter demographic patient information and the draw date and time.

This button is only active after a **Sample ID**, **Sequence No.** or a **Rack ID** and **Position** (non-barcode mode) has been entered.

See *Demographics window* on page E-211.

Barcode Read Error (barcode mode) Choose this button to display the **Barcode Read Error** window. Use this window to enter information for a non-readable barcode or a sample without a barcode.

See *Barcode Read Error window (barcode mode)* on page E-213.

Rerun Rack Assignment (non-barcode mode) Choose this button to display the **Rerun Rack Assignment** window. Use this window to assign reruns to a particular rack number and position. The assigned rack number and position are displayed in the **Rack** column on the **Data Review** screen.

See *Rerun Rack Assignment window (non-barcode mode)* on page E-214.

Repeat (non-barcode mode) Choose this button to display the **Repeat Test Selection** window. Use this window to assign the same test selections to several samples in sequence.

The Repeat function is only available when **Routine** is selected in the **Sample** area.

See *Repeat Test Selection window (non-barcode mode)* on page E-215.

Previous Use this button to display the previous sample number stored in the database. The **Test Selection** screen displays the test assignment and all other settings relating to this sample.

Next Use this button to display the next sample number stored in the database. The **Test Selection** screen shows the test assignment and all other settings relating to this sample.

Save Use this button to save the changes.

Demographics window

➔ **Workplace** > **Test Selection** or **Data Review** > **Demographics**

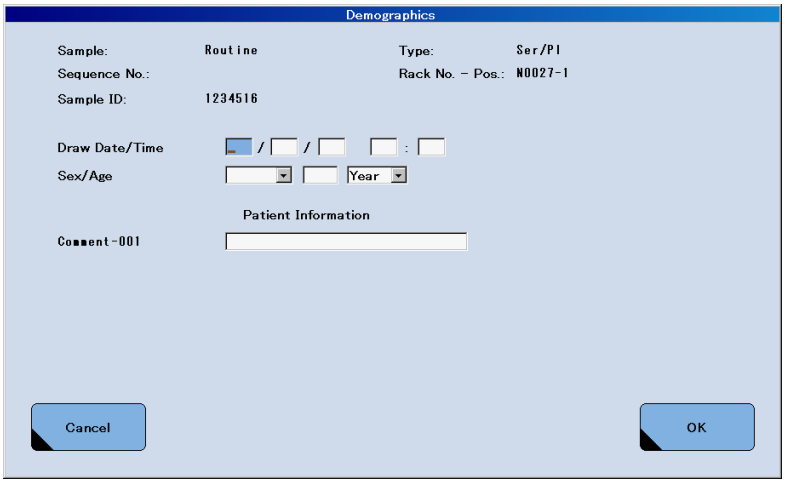


Figure E-138 Demographics window

Use this window to enter demographic information about the selected sample. The **Demographics** window is available for both STAT and routine samples. Demographic comment titles are defined on **Utility** > **System** (**Page 1/4**) > **Comment**.

See *Comment Title window* on page E-383.

Sample Information

The following information about the selected sample is automatically displayed at the top of the window:

Sample	Routine or STAT
Type	Sample type for example, Ser/Pl
Sequence No.	Sequence number (non-barcode mode)
Rack No.-Pos.	Rack No. and position of the sample
Sample ID	Sample ID number

Draw Date/Time Use these 5 text boxes to enter the date and time the sample was collected. The date/time format is defined on **Utility** > **System**. After entering a value in each text box, press <Enter> to move to the next.

Sex/Age Use these list boxes and the text box to enter the patient's sex and age. Select the patient's sex (**Male** or **Female**) from the first list box and press <Enter>. Type the patient's age (0 to 200) in the text box and press <Enter>. Select the unit of the patient´s age (**Day**, **Month**, **Year**) from the last list box and press <Enter>.

Patient Information

Use this area to enter details about the sample. Information entered here can appear on reports and in other windows or screens.

A maximum of 30 characters can be entered in the first text box, 25 in the second, 20 in the third, 15 in the fourth and 10 in the fifth. After completing each text box, press <Enter> to move to the next.

The title for the comment text box is defined on **Utility** > **System** (**Page 1/4**) > **Comment**.

See *Comment Title window* on page E-383.

Barcode Read Error window (barcode mode)

➔ **Workplace** > **Test Selection** > **Barcode Read Error**

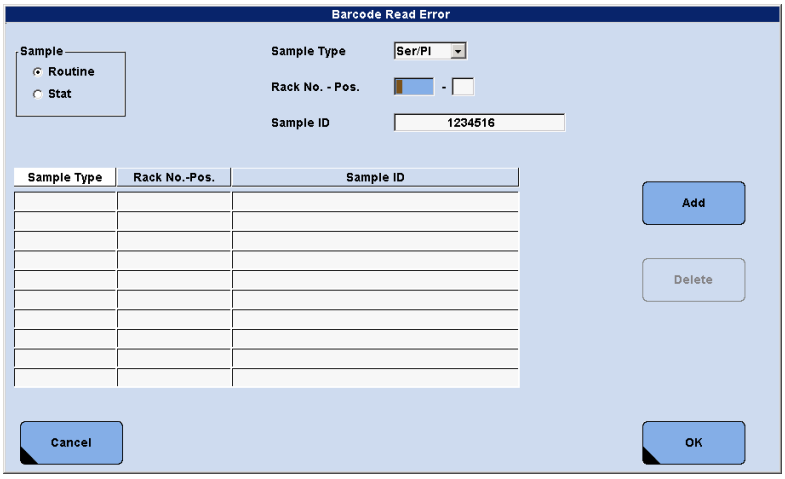


Figure E-139 Barcode Read Error window

Use this window to enter information for a sample with no or an unreadable barcode.

See *To enter a samples with unreadable barcode* on page B-86.

Sample area Use this area to indicate whether the sample is a STAT or a routine sample.

Sample Type Use this list box to select the sample type (**Ser/Pl**, **Urine**, **CSF**, **Suprnt** or **Other**).

Rack No.-Pos. Use these text boxes to define the rack number and the rack position. Type a rack number in the first text box and press <Enter>. Type the sample position number (1 to 5) in the second text box and press <Enter>.

Sample ID Use this text box to enter the sample ID (maximum 22 characters).

Sample list The sample list displays sample data which have been added in the data entry area before. This list can be sorted by **Sample Type**, **Rack No.-Pos.** or **Sample ID**. A white background distinguishes the selected column tab.

Buttons

Add Use this button to add a sample entered in the text boxes above to the sample list. After adding a sample to the sample list, the **OK** button turns yellow.

Delete Use this button to delete the sample data currently selected in the sample list after confirmation. After confirmation the **OK** button turns yellow.

The non-read position assignments are deleted once the rack(s) to which samples are assigned are scanned by the rack ID reader. Therefore, once the rack is read it can be re-used for different samples. If it is necessary to run these samples again, the position assignment must be re-entered.

Rerun Rack Assignment window (non-barcode mode)

➔ **Workplace** > **Test Selection** > **Rerun Rack Assignment**

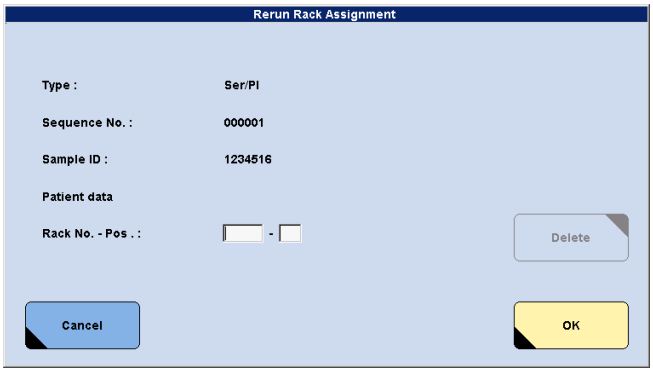


Figure E-140 Rerun Rack Assignment window

Use the **Rerun Rack Assignment** window to assign samples that require a rerun to a rerun rack and a position.

See *To assign a rerun rack* on page B-87.

Fields

Type This field displays the type of sample selected on **Workplace** > **Test Selection**.

Sequence No. This field displays the sequence number previously entered in the **Workplace** > **Test Selection** No. field.

Sample ID This field displays the ID of the sample selected on **Workplace** > **Test Selection**.

Main comment This field displays the text entered in the **Main Comment** field (for example Name) on the **Demographics** windows.

For more information, see:
Comment Title window on page E-383
Demographics window on page E-211

Rack No.-Pos. Use these 2 text boxes to enter the rack number and sample position for the rerun sample. Type a rack number in the first text box and press <Enter>. Type the sample position number (1 to 5) in the second text box and press <Enter> again.

Button

Delete Use this button to delete the current rack assignment for the selected sample ID. The current rack assignment must be deleted before a new rack assignment can be made.

Repeat Test Selection window (non-barcode mode)

➔ **Workplace** > **Test Selection** > **Repeat**

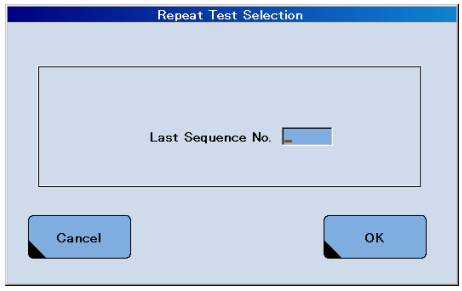


Figure E-141 Repeat Test Selection window for routine samples

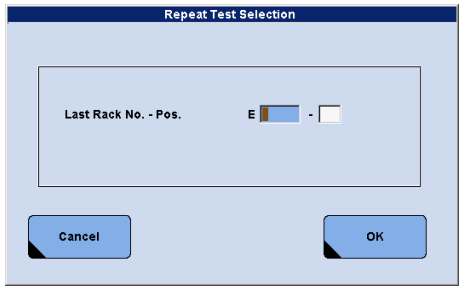


Figure E-142 Repeat Test Selection window for STAT samples

Use this window to assign the same test selections to several samples performed in sequence. Identical test selections are programmed for the specified number of samples.

Last Sequence No. (routine sample) Use this text box to enter the sequence number of the last sample to be assigned to the repeat test selection. For example, if the sequence number on **Workplace** > **Test Selection** is 1201 and you wish to program 20 more samples with the same tests, enter 1221 in this text box. The maximum number to repeat is 300.

Last Rack No. Pos. (STAT sample) Use this text boxes to enter the rack number and position of the last sample to be assigned to the repeat test selection. For example, if the rack number and position on **Workplace** > **Test Selection** is 005 - 1 and you wish to program 20 more samples with the same tests, enter 009 in the **Rack No.** text box and 1 in the **Pos.** text box. The maximum number to repeat is 300.

Data Review screen

➔ **Workplace > Data Review**

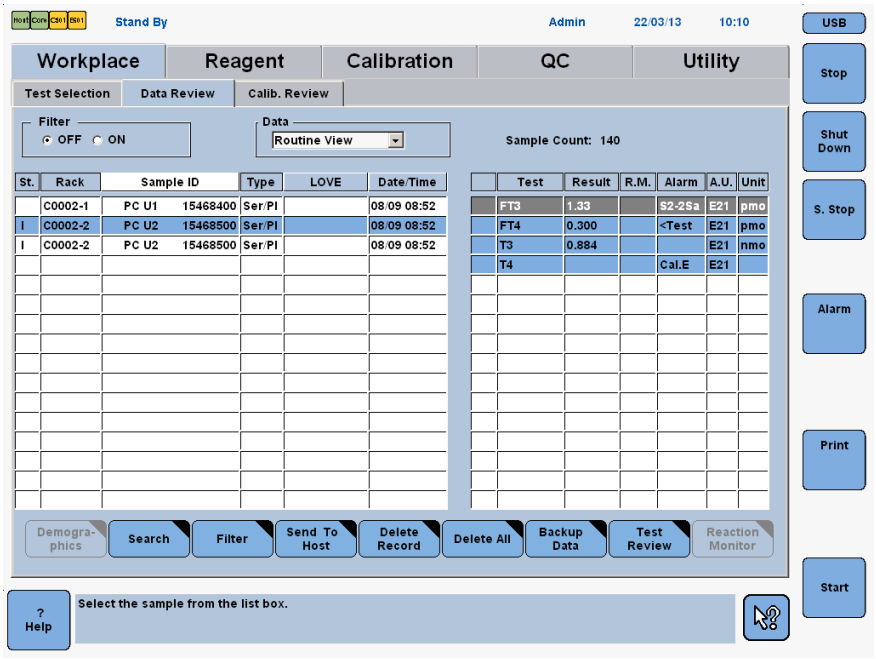


Figure E-143 Data Review screen (barcode mode)

Use this screen to perform tasks related to reviewing and editing routine and STAT results. Control results can also be viewed here. Other tasks that can be performed from this screen include editing demographic information, sending data to the Host, deleting data individually or in batches, backing up data and editing data.

For information on special operation procedures, see:
Data Review screen on page B-88
Archiving patient data on page B-91
Editing or deleting sample data on page B-93
Displaying archived patient data on page B-95

Filter area

Information that is displayed in the sample selection list can be filtered by criteria defined on **Workplace** > **Data Review** > **Filter**. Select the **ON** or **OFF** options in the **Filter** area to toggle the filter on or off, respectively.

See *Filter window* on page E-225.

Data list box

The information displayed in the sample selection list can be read either from the database (**Routine View**), the **Backup Media** or the **QC View**. Use this list box to select the medium from which data is to be read.

Routine View Select the **Routine View** option to read data from the database. This is the default.

Backup Media Select the **Backup Media** option to read data from the backup medium. Selecting this option will display the **Read Backup Disk** window. Use this window to specify the file name and medium (**Floppy Disk** or **Mass Storage**) from which patient data is to be read.

See *Read Backup Disk window* on page E-222.

QC View Select the **QC View** option to display control data in the sample selection list. The data displayed has been deleted from the database.

Clearing the sample database in **Routine View** deletes all patient results currently stored in the database and moves any control results to the **QC View**.

For more information on handling of QC results, see *QC data base management* on page B-200.

Fields

Sample Count This field displays the number of routine, control and STAT sample records listed in the database.

Sample selection list

This list on the left side of the screen displays the patient and control samples registered by the system. Its content varies depending on whether barcode, or non-barcode mode is selected on **Utility** > **System**.

The sample selection list consists of 7 columns that can be sorted by **S. No.** (only when in non-barcode mode), **Sample ID**, the main comment, and Arrived **Date/Time**. A white background distinguishes the selected column tab.

The width of the individual columns can be adjusted by clicking the column dividers in the list box head and dragging them to the left or right.

St. This column displays the sample status codes.

O (Ordered)	Sample registered by user or Host.
P (Processing)	Sample ID or rack ID has been read by barcode reader.
I (Incomplete)	Samples processed, but a data alarm is present.
No symbol (Complete)	Sample successfully processed. All test results are available without a data alarm.
H (Sent to Host)	Sample results have been sent to the Host.
#	Sample has been pipetted on **c** 501. Note that additional measurements on the **e** 601 might be affected by carryover (see following note).
b	Sample has been processed on **c** 501. A special wash for the sample probe of the **c** 501 has been performed before the sample was pipetted.

Possible sample carryover when measuring high-priority elecsys (HPE)

If HPE tests are requested for a sample, this sample is pipetted on the **e** 601 module prior to pipetting on **c** 501 module.

If a sample has already been processed on the **c** 501 module, a #-flag is displayed on the **Data Review** screen. This indicates the risk of potential carryover if sample from this sample container is used for additional or rerun HPE requests.

If a #-flag is displayed, always use newly aliquoted samples to perform manual reruns of high-priority elecsys.

For control samples only the following statuses are available: P, I, H and no symbol (complete).

Rack This column displays the rack number and sample position within the rack for the current sample.

Sample ID This column displays the sample identification and for controls additionally the lot number.

Type This column displays the sample type (**Ser/Pl**, **Urine**, **CSF**, **Suprnt** or **Other**).

Comment-001 This column displays the main comment entered for the sample.

For more information, see:
Demographics window on page E-211
Comment Title window on page E-383

Date/Time This column displays the date and time the sample was registered by the system. The format is defined on **Utility** > **System**.

S. No. (non-barcode mode) This column displays the sample categories: **N** for normal or routine, **E** for emergency or STAT, and **C** for control, and the sequence number of the sample.

For example: N00203 identifies the sample as a routine sample with sequence number 203.

Test results list

This list appears on the right side of the screen and displays the results of the tests performed on the patient or control sample currently selected in the sample selection list. The results are displayed as soon as they are available.

If an add-on test is ordered for a sample it is displayed as ordered and a volume symbol in the first column to the left of the **Test** column is displayed.

Test This column displays the test(s) processed for the currently selected sample. As long as the sample status is *Ordered* or *Processing* a symbol is displayed.

A symbol for the volumes to be used is displayed to the left of the test name.

These volumes are defined on **Utility** > **Application** > **Analyze**. The symbol for the volumes disappears as soon as the result is generated.

■ (Dark blue): Indicates a test to be run with normal sample concentration.

▲ (Dark blue): Indicates a test is marked to be run with an increased sample concentration. This applies to photometric assays (**c** 501 module) only.

▼ (Dark blue): Indicates a test is marked to be run with a decreased sample concentration. This applies to photometric assays and ISE tests (**c** 501 module) only. For ISE tests only urine samples can be run with decreased volume.

▽ (White): Indicates a test is marked to be run with a diluted sample.

\# A hash (#) indicates a sample with potential sample carryover. This sample has been processed on a **c** 501 in the first run. In a possible second run a test is requested which would have required a special wash for the sample probe of the **c** 501 module. The hash (#) appears as a warning for a potential sample carryover together with the *Samp.O* alarm.

- If a test has already run twice and a third request is made, the result of the second run is replaced by the result of the third run. An additional run (3rd, 4th, and so on) is only possible, if the previous result has been uploaded to the Host.
- If Host communication is not available, it is not possible to use **3rd Results Acceptance**.
- Please note the number of runs (1st, Rerun) is tests-oriented, not sample-oriented.

Result This column displays the results for the selected sample.

R.M. This column displays a result message (**R.M.**). Reactive (**r**), non reactive (**n**) or borderline (**b**) indicates if a test for a qualitative assay has a positive, negative or borderline result, respectively.

Alarm This column displays any data alarm associated with the result of the test for the selected sample. The displayed data alarm depends on the data alarm priority.

For more information, see:
Data alarm priority on page D-8
Data alarm list on page D-10

A.U. This column displays the analytical unit (analytical module) for the test of the selected sample.

Unit This column displays the unit (for example g/L, U/ml or U/L) of the test for the selected sample.

Buttons

Demographics Choose this button to display the **Demographics** window. Use this window to enter and view demographic patient information and the draw date and time. A sample must be selected from the sample selection list for the **Demographics** button to be active.

See *Demographics window* on page E-211.

Search Choose this button to display the **Search Sample** window. Use this window to search for a sample using specified search criteria.

See *Search Sample window* on page E-223.

Filter Choose this button to open the **Filter** window. Use this window to define criteria to filter information displayed on the sample selection list.

See *Filter window* on page E-225.

Send To Host Choose this button to display the **Send To Host** window. Use this window to define which data to send to the Host.

See *Send To Host window* on page E-227.

Delete Record In the **Routine** view, use this button to delete sample records, including results and test selections, without altering the sample count, after confirmation. QC results are moved to the **QC View**.

In the **QC View**, use this button to delete the selected QC results from the **Data Review** (**QC View**) screen and the **QC** > **Individual** screen.

For more information, see *QC data base management* on page B-200.

Delete All In the **Routine** view, use this button to delete all sample records, including results and test selections. After confirmation the sample count returns to 0. QC results are moved to the **QC View**.

In the **QC View** the **Delete** button offers two options:

- **Individual Delete**
 - All QC results are deleted from the **Data Review** (**QC View**) screen.
 - All QC results are also deleted from the **QC** > **Individual** screen.
- **Delete All**
 - All QC results are deleted from the **Data Review** (**QC View**) screen.
 - All QC results are also deleted from the **QC** > **Individual** screen.
 - Additionally, all QC results are deleted from **Data Review** (Routine view) screen.

For more information, see *QC data base management* on page B-200.

Backup Data Choose this button to display the **Backup Data** window. Use this window to store data.

See *Backup Data window* on page E-230.

Test Review Choose this button to open the **Test Review** window. Use this window to review and edit test results.

See *Test Review window* on page E-232.

Reaction Monitor Choose this button to display the **Reaction Monitor** window. Use this window to view the reaction graph for a specific test on a specific sample.

See *Reaction Monitor window* on page E-240.

Read Backup Disk window

➔ **Workplace** > **Data Review** > **Data** (list box) > **Backup Media**

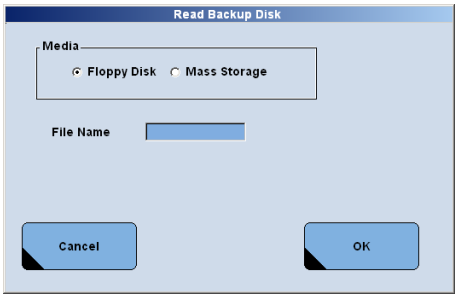


Figure E-144 Read Backup Disk window

Use this window to enter a file name.

Only data saved in binary format can be read by the system.

File Name Use this text box to enter the name of the file to be read (up to 8 characters).

Media area

Use this area to select the medium where the data was stored.

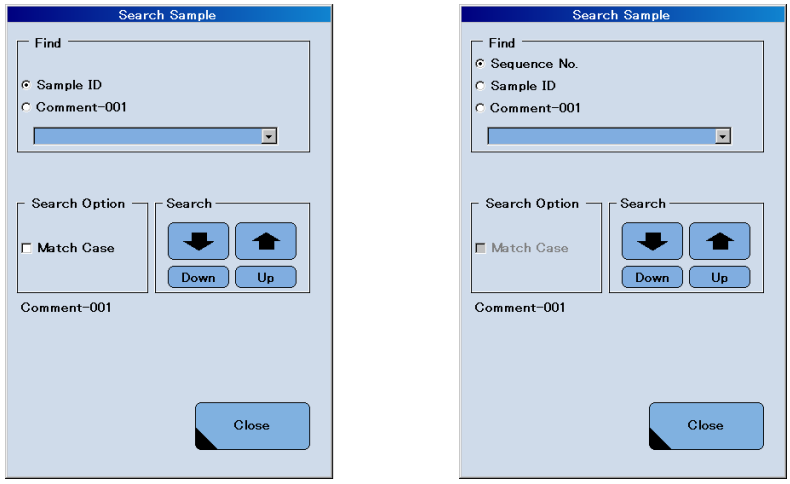
Option	Description
Floppy Disk	Select this option to read the data from a floppy disk.
Mass Storage	Select this option to read the data from a mass storage. If a **USB** storage device is inserted, the instrument uses the USB as mass storage. If no USB storage device is inserted, the instrument uses a DVD disk as mass storage.

Table E-9 Media area

For more information, see *Data storage* on page B-244.

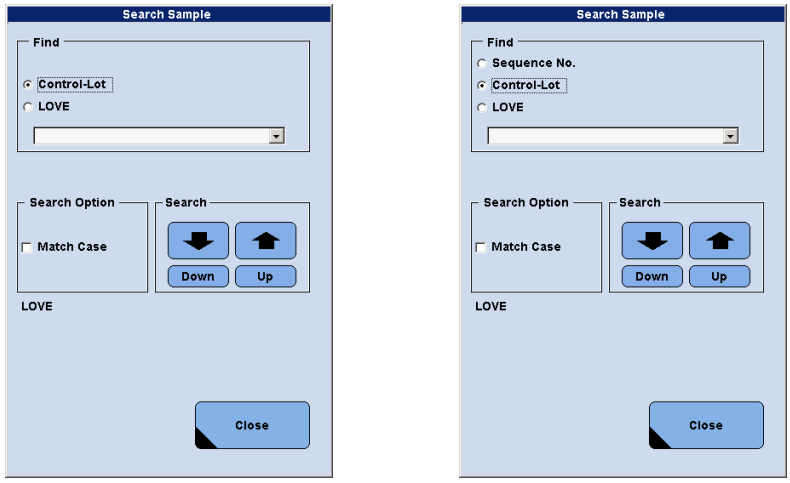
Search Sample window

➔ **Workplace > Data Review > Search**



A Barcode mode **B** Non-barcode mode

Figure E-145 Search Sample window for Routine View



A Barcode mode **B** Non-barcode mode

Figure E-146 Search Sample window for QC View

Use this window to search for a sample in the database. Search criteria and options, such as sequence number and sample number, are defined using this window. The **Sample Search** window is an overlay on the right-hand side of the **Data Review** screen thereby allowing you to view both the window and the search results at the same time.

Find area

Use this area to select the search criteria, such as sequence number and sample number.

Sequence No. (non-barcode mode) Select the **Sequence No.** option to search for a sample by sequence number. When this option is selected, the adjacent list box is available. Select the sequence number from the list, or enter all or a part of the sequence number to be searched for.

Sample ID (Routine View) Select the **Sample ID** option to search by sample ID. When selected, the adjacent list box is available. Select the sample identification from the list, or enter the sample identification or a part of the sample number to be searched for.

The **Sample ID** option is only available if **Routine View** or **Backup Media** is selected on the **Workplace** > **Data Review** screen.

Control-Lot (QC View) Select the **Control-Lot** option to search by control lot. When selected, the adjacent list box is available. Select the control lot number from the list, or enter the control lot number or a part of the control lot number to be searched for.

The **Control-Lot** option is only available if **QC View** is selected on the **Workplace** > **Data Review** screen.

Main Comment Select the **Main Comment** option to search by main comment. The main comment title is defined on **Utility** > **System** (**Page 1/4**) > **Comment**. When selected, the adjacent list box is available. Enter the comment or a part of the comment to search for.

See *Comment Title window* on page E-383.

Search Option area

Match Case Select the **Match Case** check box to activate case sensitivity. This check box is not available if the **Sequence No** option is selected.

Search area

Down (barcode mode) Choose either the **Down** button or the down arrow to search the sample list of the **Data Review** screen down from currently selected sample.

Up (barcode mode) Choose either the **Up** button or the up arrow to search the sample list of the **Data Review** screen up from currently selected sample.

Main Comment This field displays the information for the main comment for the sample found in the sample list matching the specified search criteria. The main comment title is defined on **Utility** > **System** (**Page 1/4**) > **Comment**.

See *Comment Title window* on page E-383.

Filter window

➔ **Workplace** > **Data Review** > **Filter**

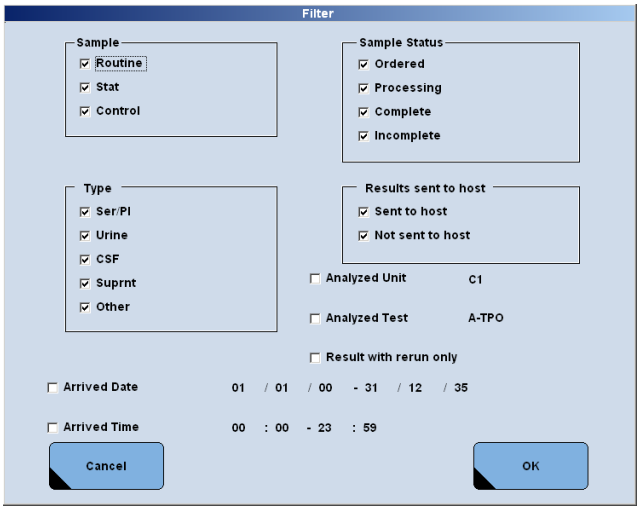


Figure E-147 Filter window

Use this window to define filter criteria used to filter the information displayed in the sample selection list. The filter settings stay as defined by the operator, until they are changed by the operator.



The filter can be toggled on and off in the **Filter** area at the top left corner of the **Data Review** screen.

See *Filter area* on page E-217.

Sample area Use this area to filter results by sample type. The available options are: **Routine**, **STAT** and **Control**.

Sample Status area Use this area to filter results by status of sample processing. The available options are: **Ordered**, **Processing**, **Complete** and **Incomplete**.

Type area Use this area to filter results by sample material. The available options are: **Ser/Pl**, **Urine**, **CSF**, **Suprnt** and **Other**.

Results sent to host area Use this area to filter results by sent to Host status. The available options are: **Sent to host** and **Not sent to host**.

Analyzed Unit Use this option to filter results by module. For **e** 601 the measuring channel is also displayed. Select the check box to activate the adjacent list box.

Analyzed Test Use this option to filter results by test. Select the check box to activate the adjacent list box. All tests available on the system are displayed in this list box.

Result with rerun only Use this option to filter results with reruns only.

Arrived Date Use this option to filter results within a defined arrival date range. To define the range, enter the start date in the first 3 text boxes and the end date in the final 3 text boxes. The date format is defined in the **Date and Time Setting** area under **Utility** > **System**.

Arrived Time Use this option to filter results within a defined arrival time range. To define the range, enter the start time in the first 2 text boxes and the end time in the final 2 text boxes (the time format is hh:mm).

Send To Host window

➔ **Workplace** > **Data Review** > **Send To Host**

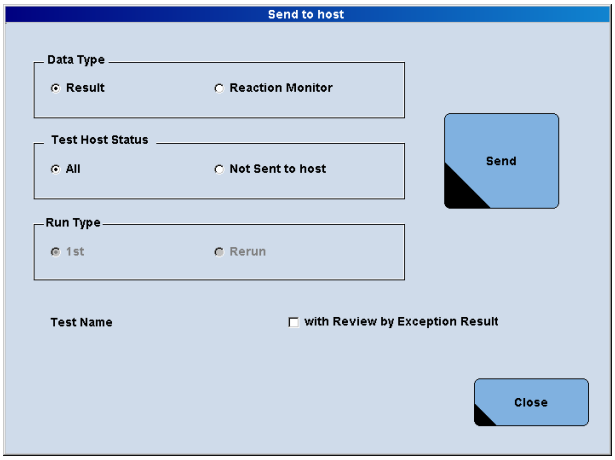


Figure E-148 Send To Host window

Use this window to send data to the Host. All or specific types of sample results can be transmitted to the Host.

Highlight the samples to be sent to the Host in the sample list on **Workplace** > **Data Review**, then choose **Send To Host**.

Data Type area

Result Select the **Result** option to send the final result to the Host. When this option is selected, the **Test Host Status** area is enabled and the **Run Type** area is disabled.

Reaction Monitor Select the **Reaction Monitor** option to send raw data for each measuring point to the Host. When the **Reaction Monitor** option is selected, the **Run Type** area and **Test Name** list box are enabled.

Test Host Status area

This area is active only if **Result** has been selected in the **Data Type** area.

All Select the **All** option to send all data to the Host.

Not Sent to Host Select the **Not Sent to host** option to send only results that have not already been sent to Host.

Run Type area



This area is active only if the **Reaction Monitor** option has been selected in the **Data Type** area.

1st Select the **1st** option to send first run results to the Host.

Rerun Select the **Rerun** option to send rerun results to the Host.

Fields

Test Name Use this box to specify a reaction monitor to be sent to the Host. This box is available only if **Reaction Monitor** is selected in the **Data Type** area. Choose the **Test Name** box to open a test list and select the test whose reaction monitor is to be sent.

See *Data Type area* on page E-227.

With Review by Exception Result Use this check box to send data to the host even if they are flagged with an alarm. This check box is only available if **Result** is selected in the **Data Type** area. The data alarms that normally prevent a result from being sent to the host are listed under **Utility** > **System** > **Review by Exception**.

For more information, see:
Data Type area on page E-227
Review By Exception window on page E-419

Button

Send Use this button to start the transmission of the specified sample results or reaction monitor to the Host.

Delete All window

➔ **Workplace** > **Data Review** > **QC View** > **Delete All**

Use this window to delete QC results. The **Delete All** window offers two options:

- **Individual Delete**
 - All QC results are deleted from the **Data Review** (**QC View**) screen.
 - All QC results are also deleted from the **QC** > **Individual** screen.
- **Delete All**
 - All QC results are deleted from the **Data Review** (**QC View**) screen.
 - All QC results are also deleted from the **QC** > **Individual** screen.
 - Additionally, all QC results are deleted from **Data Review** (Routine view) screen.

For more information, see *QC data base management* on page B-200.

Backup Data window

➔ **Workplace** > **Data Review** > **Backup Data**or **System Overview** > **Sample Data Clear** > **Backup and Clear**

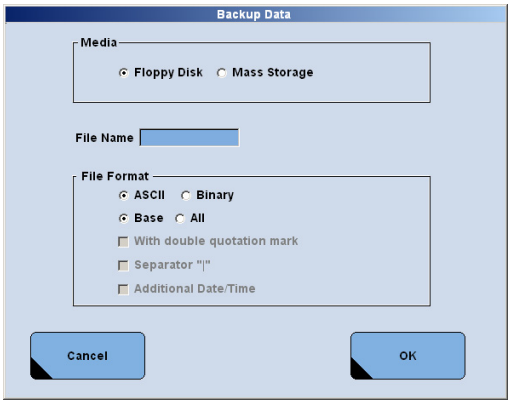


Figure E-149 Backup Data window

Use this window to copy results selected in the sample list on **Workplace** > **Data Review** to a special File Format.

Only data saved in binary format can be restored using **Workplace > Data Review > Backup Data**.

- ASCII files can be read by other PC systems, but cannot be reloaded into the system.
- With the **Filter** function enabled in the **Data Review** screen, only filtered data will be stored.

File Name Use this text box to define the file name under which the results are saved. Type an appropriate file name, with up to 8 characters, and press <Enter>.

For more information, see *Archiving patient data* on page B-91.

Media area

In this area you can select the destination medium where the data is stored.

Floppy Disk Select **Floppy Disk** to store the data on a floppy disk in the floppy disk drive of the control unit's computer.

Mass Storage Select **Mass Storage** to store the data on a mass storage.

- If a **USB** storage device is inserted, the instrument uses the USB as mass storage.
- If no USB storage device is inserted, the instrument uses a **DVD** disk as mass storage.

For more information, see *Data storage* on page B-244.

File Format area

ASCII Select the **ASCII** option to write patient results to a disk in ASCII format. This is a flexible format that can be used by other PC systems, for example, in a spread sheet program, but cannot be restored to the **cobas** 6000 system.

Binary Select the **Binary** option to write patient results to the disk in binary format. This format cannot be read by other PC systems but can be restored to the **cobas** 6000 system.

See *Displaying archived patient data* on page B-95.

Base When the **Base** option is selected, no data from **e** 601 tests are stored. This option is only available, if the **cobas** 6000 system is equipped with a **c** 501 module.

All When the **All** option is selected, data from **e** 601 tests and **c** 501 tests are stored.

With double quotation mark Select the **With double quotation mark** option to use double quotation marks as text separator in the generated ASCII file.

Separator "\|" Select the **Separator "\|"** option to use the ASCII character "|" as field separator in the generated ASCII file. If this option is not selected, a comma (,) is used to separate fields in the generated ASCII file.

Additional Date/Time Select the **Additional Date/Time** option to add the sampling date and time as an additional field in the generated ASCII file.

Button

OK Choose this button to start the backup process after confirmation.

After confirmation that the backup process has started, the message **IN PROCESS, PLEASE WAIT** is displayed. Wait until this message disappears before continuing.

Test Review window

The **Test Review** window is different depending on the selected sample.

Test Review window for patient samples

➔ **Workplace** > **Data Review** > patient sample (in sample list) > **Test Review**

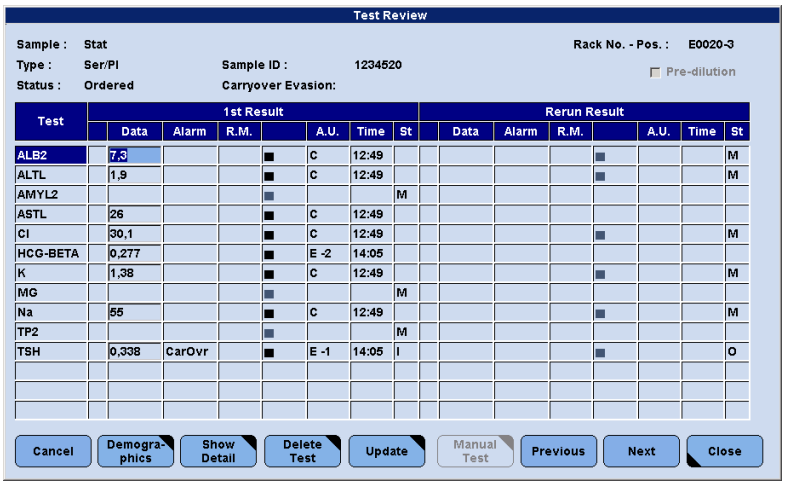


Figure E-150 Test Review window

Use this window to review and edit test results.

Sample Data area

Sample This field displays the sample type (for example, **STAT**, **Routine**, **Control**) of the sample selected on **Workplace** > **Data Review**.

Sequence No. (non-barcode mode) This field displays the sequence number of the sample selected sample on **Workplace** > **Data Review**.

Rack No.-Pos. This field displays the rack ID and the position of sample selected on **Workplace** > **Data Review**.

Type This field displays the sample material of the sample selected on **Workplace** > **Data Review** (**Ser/Pl**, **Urine**, **CSF**, **Suprnt** or **Other**).

Sample ID This column displays the sample identification.

Status This field displays the sample status (**Ordered**, **Processing**, **Complete**, **Incomplete** or **Sent to Host**).

Pre-dilution This check box is selected if the sample was defined as pre-diluted on **Workplace** > **Test Selection**.

👁 For more information, see *Pre-dilution* on page E-205.

Carryover Evasion This field displays the detergents for the special wash.

For more information, see:
Special Wash on page B-297
Special Wash screen on page E-528

Test result list

This list shows all tests of the sample selected on **Workplace** > **Data Review**. The list is divided into **1st Result** and **Rerun Result**.

Test This column displays the short name of the test. If both the 1st and rerun result is available, operators can select the result to report.

Color markings The following color markings are displayed to the right of the test name:

White: indicates that 2 results are available. The result can be selected.

Blue: square indicates that the result has been selected.

Green: indicates that the result has been selected.

In case two results are available, one has to be selected for upload (batch upload). The marking turns from white to green.

Red: indicates a Review by exception flag appeared. The result is not sent to the Host.

See *Review By Exception window* on page E-419.

Yellow: indicates the test is part of a compensated test formula.

The test itself was not requested via Host or test selection screen. It was automatically done because it is part of a test formula.

For more information, see:
Programming compensated tests on page B-295
Calculated Test screen on page E-520

Data This column displays the test result.

Values in the Data column can be edited.

Alarm This column displays any data alarms associated with test result.

See *Data alarm list* on page D-10.

R.M. This column displays a result message (**R.M.**). Reactive (**r**), non reactive (**n**) or borderline (**b**) indicates if a test for a qualitative assay has a positive, negative or borderline result, respectively.

(Dil.) This column displays the sample dilution ratio used to produce the test result.


(Dark blue): Indicates a test to be run with normal sample concentration.


(Dark blue): Indicates a test is marked to be run with an increased sample concentration. This applies to photometric assays (**c** 501 module) only.


(Dark blue): Indicates a test is marked to be run with a decreased sample concentration. This applies to photometric assays and ISE tests (**c** 501 module) only. For ISE tests only urine samples can be run with decreased volume.


(White): Indicates a test is marked to be run with a diluted sample.

\# A hash (#) indicates a sample with potential sample carryover. This sample has been processed on a **c** 501 in the first run. In a possible second run a test is requested which would have required a special wash for the sample probe of the **c** 501 module. The hash (#) appears as a warning for a potential sample carryover together with the *Samp.O* alarm.

A.U. This column displays the analytical unit (analytical module) used for the particular sample (for example, E2-1 for **e** 601 2, measuring channel 1).

Time This column displays the time the test was sampled.

St. This column displays the status code of the test result.

O (Ordered)	Test requested by user or Host.
P (Processing)	Sample ID or rack ID has been read by core.
I (Incomplete)	Test processed, but a data alarm is present.
No symbol (Complete)	Test successfully processed.
H (Sent to Host)	Test results have been sent to the Host.
M (Masked Test)	Test has been masked due to an abnormality during processing. Displayed only on **Workplace** > **Data Review** > **Test Review**.
	Test has not been performed due to missing diluent.
E (Edited Test)	Test results have been manually edited on **Workplace** > **Data Review** > **Test Review**.

Test Review window for QC samples

➔ **Workplace** > **Data Review** > QC sample (in sample list) > **Test Review**

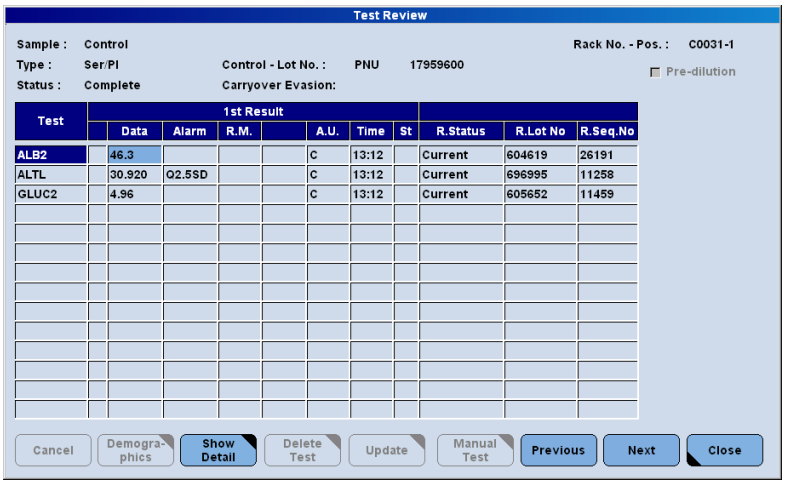


Figure E-151 Test Review window

Use this window to review and edit results of QC samples.

Sample Data area

Sample This field displays the sample type (**Control**) of the sample selected on **Workplace** > **Data Review**.

Sequence No. (non-barcode mode) This field displays the sequence number of the sample selected sample on **Workplace** > **Data Review**.

Rack No.-Pos. This field displays the rack ID and the position of the QC sample selected on **Workplace** > **Data Review**.

Type This field displays the sample material of the QC sample selected on **Workplace** > **Data Review**.

Control - Lot No. This column displays the name and the lot number of the control.

Status This field displays the sample status (**Processing**, **Complete**, **Incomplete** or **Sent to Host**).

Carryover Evasion This field displays no information for QC samples.

Test result list

This list shows all tests of the control sample selected on **Workplace** > **Data Review**. For control samples the list shows only the results of the first run (**1st Result**).

Test This column displays the short name of the test.

Data This column displays the test result.

Alarm This column displays any data alarms and data alarms for controls associated with test result.

See *Data alarm list* on page D-10.

R.M. This column displays a result message (**R.M.**). Reactive (**r**), non reactive (**n**) or borderline (**b**) indicates if a test for a qualitative assay has a positive, negative or borderline result, respectively.

A.U. This column displays the analytical unit (analytical module) used for the particular sample (for example, E2-1 for second **e** 601 module, measuring channel 1).

Time This column displays the time the test was pipetted.

St. This column displays the status code of the test result.

P (Processing)	Sample ID or rack ID has been read by core.
I (Incomplete)	Samples processed, but a data alarm is present.
No symbol (Complete)	Samples successfully processed.
H (Sent to Host)	Sample result has been sent to the Host.

R.Status This column displays the reagent status **Current** or **SB** (standby).

R. Lot No. This column displays the reagent lot number. For ISE tests, the IS reagent position is displayed.

R. Seq. No. This column displays the reagent sequence number. For ISE tests, no information is displayed.

- For current reagents, the lot and sequence (serial) numbers are displayed after the measurement is completed.
- For standby reagents, the lot and sequence (serial) numbers are displayed after the test has been pipetted.

Buttons

Cancel Choose this button to reset edited data to the original value before choosing **Update**.

Demographics Choose this button to display the **Demographics** window. Use this window to enter and view demographic patient information and the draw date and time for the current sample. A sample must be selected from the sample selection list for the **Demographics** button to be active.

See *Demographics window* on page E-211.

Show Detail Choose this button to open the Detail window. This window displays detailed information about the selected test.

See *Detail window* on page E-238.

Delete Test Choose this button to delete the selected test results after confirmation.

Update Choose this button when it is highlighted in yellow to update the data in the **Test Result** list.

Manual Test Choose this button to display the **Manual Test** window. From this window you can manually enter data for a test that has not been processed or measured on the system.

See *Manual Test window* on page E-239.

Previous Use this button to display the test results for the previous sample.

Next Use this button to display the test results for the next sample.

Detail window

➔ **Workplace** > **Data Review** > **Test Review** > **Show Detail**



Figure E-152 Detail window

Use this window to review details of the test results currently selected in the **Test Review** window. In the upper area the window displays the details for the first result and in the lower area for the rerun result.

Analyzed Unit This field displays the module on which the test was performed and the measuring channel on the **e** 601.

Effective Signal This field appears in an **e** 601 test review only; it displays the effective signal measured.

Sampling Date This field displays the date and time the test was pipetted.

Used Reagents This field displays the lot number and the sequence (serial) number of the reagent used for the measurement. For tests performed on an **e** 601, the ProCell lot number is also displayed. The position number refers to the ProCell bottle used.

Manual Test window

➔ **Workplace** > **Data Review** > **Test Review** > **Manual Test**

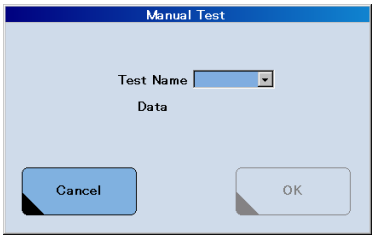


Figure E-153 Manual Test window

Use this window to manually enter data for a test that has not been processed or measured on the system.

Test Use this list box to select a test that has not been processed or measured on the system.

Only **c** 501 module tests that are installed and inactive in **Utility** > **Application** > **Range** can be selected here.

Data Use this field to enter data manually.

Reaction Monitor window

➔ **Workplace** > **Data Review** > **Reaction Monitor**

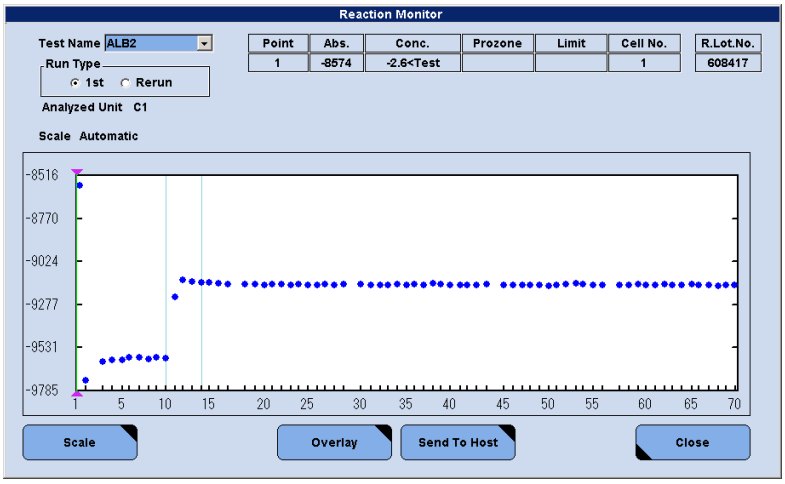


Figure E-154 Reaction Monitor window (Photometric unit)

Use this window to view the reaction graph for a specific test for the selected sample. The graph displayed represents the sample and test selected on the **Data Review** screen. Both the original and rerun results for patient samples can be viewed. Different tests for the selected sample may be viewed by using the **Test Name** list box.

Test Name Use this list box to select the test to be displayed on the graph. The test selected on the **Data Review** screen is automatically displayed. Select the desired test from the list box.

Analyzed Unit This field displays the module on which the test was performed.

Scale This field displays the scale, **Automatic** or **Manual**, selected on the **Scale Setting** window.

1st Select the **1st** option to view the reaction graph for the results from the first run of the specified test.

Rerun Select the **Rerun** option to view the reaction graph for the results from the rerun of the specified test, if available.

Reaction information

Point The **Point** column shows the individual measuring point selected in the graph.

Abs. The **Abs.** column displays the absorbance value for the measuring point displayed in the Point column and selected on the graph.

Conc. The **Conc.** column displays the result (concentration) of the selected test.

Prozone The **Prozone** column displays the prozone check value.

For more information, refer to the COBI CD.

Limit The **Limit** column displays the corrected test-specific reaction limit. This is only displayed for rate assays.

For more information, refer to the COBI CD.

Cell No. The **Cell No.** column displays the reaction cell number where the reaction took place.

R.Lot.No. The **R.Lot.No.** field displays the lot number of the reagent bottle.

Graph area

This area displays the graph of the selected test. Use the scroll bar to move to and display the information for the selected point on the graph. The pink triangles represent the selected measuring point. The light blue bars represent the measuring points defined under **Utility** > **Application** > **Analyze**.

Buttons

Scale Choose this button to display the **Scale Setting** window. Use the **Scale Setting** window to define the lower and upper limits of the absorbance range shown on the Y-axis of the graph.

See *Scale Setting window* on page E-242.

Overlay Choose this button to display the **Overlay** window. Use the **Overlay** window to select up to 5 samples or controls for a specified test. The **Reaction Monitor** window displays all selected graphs at the same time.

See *Overlay window* on page E-243.

Send To Host Choose this button to display the **Send To Host** window. Use the **Send To Host** window to send reaction monitor data to the Host computer.

See *Send To Host window* on page E-227.

Scale Setting window

➔ **Workplace** > **Data Review** > **Reaction Monitor** > **Scale**

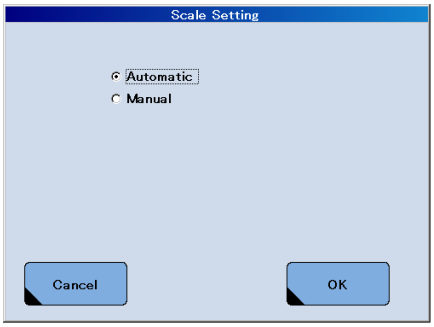


Figure E-155 Scale Setting window

Use the **Scale Setting** window to define the lower and upper limits of the absorbance range that is shown on the Y-axis of the graph.

Automatic Select the **Automatic** option to allow the system to automatically set the scale.

Manual Select the **Manual** option to set the scale manually. Setting the scale manually improves the resolution of the graph. Type the value of the lower limit of the scale (-10000 to 40000) in the first text box and press <Enter>. Type the value of the upper limit of the scale (-10000 to 40000) in the second text box and press <Enter>.

Overlay window

➔ **Workplace** > **Data Review** > **Reaction Monitor** > **Overlay**

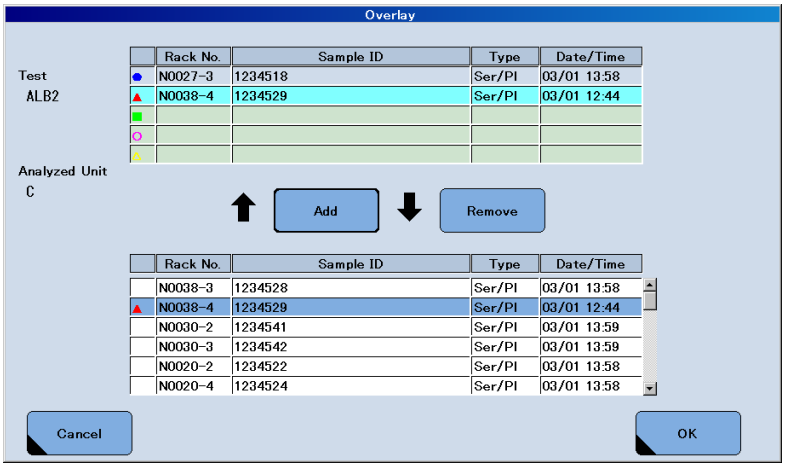


Figure E-156 Overlay window

Use the **Overlay** window to select up to 5 samples for a specified test. The **Reaction Monitor** window displays all selected graphs at the same time.

See *Reaction Monitor window* on page E-240.

This window is useful in comparing reaction curves of up to 5 samples or controls for a specific test. The results can assist in troubleshooting potential system or sample problems by showing the relationship of results from one sample or control to another for a given test.

Test This field displays the name of the test for which reaction graphs are being selected for overlay.

Symbol list box This list box has 5 columns in non-barcode mode and 4 columns in barcode mode. Select the symbol in the top list box. Then select the sample for which you wish to overlay the reaction graph from the sample list box. Choose the **Add** button to add the sample to the top list box. You can choose up to 5 samples to overlay by selecting a new symbol for each sample. The Symbol list box assigns a symbol to the reaction graph for interpretation on the **Reaction Monitor** window.

Sample list box This list box contains the same columns as the Symbol list box at the top of the window: **Sequence No.** (non-barcode mode), **Rack No.** (barcode mode), **Sample ID** and **Type**.

Select the sample to be added to the selected symbol in the Symbol list box. Choose the **Add** button to add this sample to the Symbol list box. The symbol is displayed in the Sample list box to the left of the **Sequence No.** in non-barcode mode and the **Rack No.** in barcode mode.

Sequence No. (non-barcode mode) This column displays the ID number of the sample selected for overlay.

Rack No. This column displays the rack ID number of the sample selected for overlay.

Sample ID This column displays the patient ID of the sample selected for overlay.

Type This column displays the sample type (**Ser/Pl**, **Urine**, **CSF**, **Suprnt** or **Other**) of the sample selected for overlay.

Date/Time This column displays the time when the sample passed the barcode reader.

Buttons

Add Use this button to add a sample selected from the Sample list box at the bottom of the window to the Symbol list box at the top of the window. Choose the desired symbol in the Symbol list box. Choose the desired sample in the Sample list box. Then choose the **Add** button to add the sample to the Symbol list box. Repeat up to 5 times.

Once the sample is added to the symbol list box, the symbol is also displayed in the Sample list box to the left of the **Sequence No**. in non-barcode mode or the **Rack No.** in barcode mode.

Remove Use this button to remove a sample listed in the Symbol list box at the top of the window. Choose the desired sample in the Symbol list box, then choose the Remove button to delete the sample from the Symbol list box.

The symbol is also removed from the sample in the Sample list box.

Calib. Review screen

➔ **Workplace** > **Calib. Review**

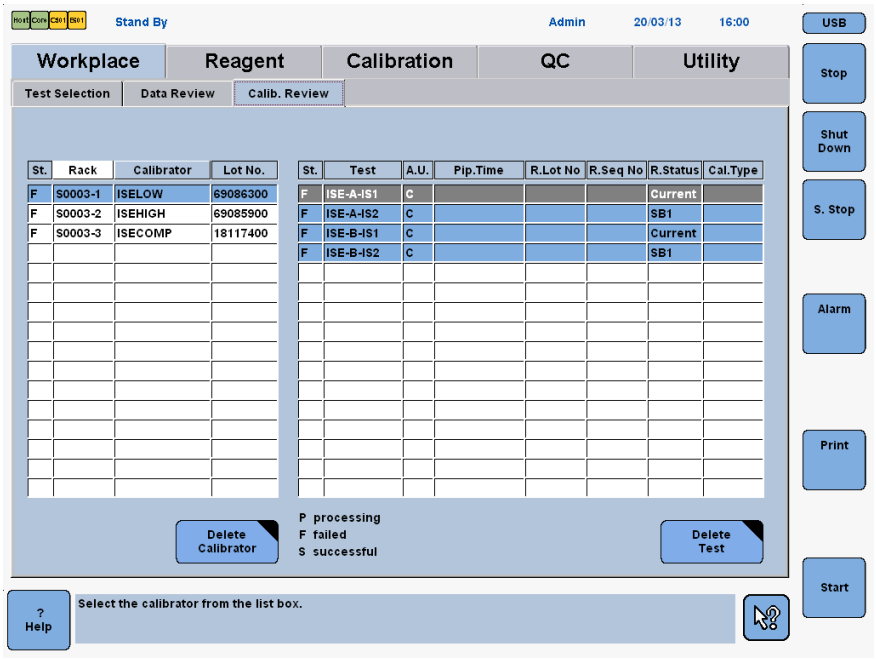


Figure E-157 Calib. Review screen

Use this screen to review the status of the calibrators that are currently in process and the status of the calibrations.

The information generated on this screen is automatically deleted if the analyzer is shutdown or goes into Sleep status. When the analyzer is in standby, it is also possible to delete any calibrator with the **Delete Calibrator** button or a calibration test with the **Delete Test** button.

👁 For information about calibration as part of daily routine operations, see *Calibration and QC Select button* on page B-51.

👁 For detailed information on special operations, see *Deleting a calibrator or a calibrated test* on page B-97.

Calibrator selection list

The list on the left side of the screen displays the calibrators registered by the analyzer.

The calibrator selection list consists of 4 columns that can be sorted by **Rack** or **Calibrator**. A white background distinguishes the selected column tab.



The width of the individual columns can be adjusted by clicking the column dividers in the list box head and dragging them to the left or right.

St. This column displays the calibrator status codes.

P (Processing)	The calibrator is registered by the analyzer (barcode is already read) and at least one calibration is processing for this calibrator.
F (Failed)	At least one of the calibrations performed with this calibrator could not generate a valid calibration.
S (Successful)	Calibrator successfully processed. All calibrations performed with this calibrator have generated valid results.

Rack This column displays the rack number and calibrator position within the rack for the current calibrator. The calibrator position is displayed for **c** 501 tests (photometric and ISE) only.

Calibrator This column displays the calibrator name.

Lot No. This column displays the calibrator lot number.

Test results list

The list on the right side of the screen displays detailed information for the tests performed with the calibrator currently selected in the calibrator selection list.



The width of the individual columns can be adjusted by clicking the column dividers in the list box head and dragging them to the left or right.

St. This column displays the calibration status codes.

P (Processing)	The calibrator for the test is registered by the analyzer (barcode is already read) and at least one calibration is requested for this calibrator. If the calibrator has already been pipetted by the analyzer, a pipetting date and time is available.
F (Failed)	No valid calibration has been generated for the test.
S (Successful)	A valid calibration has been generated for the test.

Test This column displays the test name processed for the currently selected calibrator.

For ISE tests this column displays the ISE type (**ISE-A** or **ISE-B**) and ISE reagent position (IS1 or IS2).

A.U. This column displays the analytical unit (analytical module) for the test of the selected calibrator (for example, **E2-1** for **e** 601 2, measuring channel 1).

Pip. Time This column displays the latest pipetting date and time of the test. The date/time format is defined on **Utility** > **System**. The date and time are updated by a new pipetting of the calibrator.

R. Lot No. This column displays the reagent lot number of the test. In case of ISE tests, no information is displayed.

R. Seq. No. This column displays the reagent sequence number of the test. In case of ISE tests, no information is displayed.

R. Status This column displays the reagent status (**Current** or standby **SB1**, **SB2** …) of the test.

Cal. Type This column displays the calibration type **Lot** for a lot calibration or **R.Pack** for a reagent pack calibration.

In case of ISE tests, no information is displayed.



If a calibration for the same test and for the same reagent is measured again, the information in the row of this test will be overwritten.

Buttons

Delete Calibrator Use this button to delete any calibrator selected in the calibrator selection list.

Delete Test Use this button to delete any test of a calibrator selected in the test result list.

Calib. Review screen

Reagent menu

Use the **Reagent** menu to view the reagent information and the reagent status. You can also get some information about the system reagents and the auxiliaries.

In this chapter *Chapter* 24

Setting screen E-251
Setting screen list E-252
Buttons E-254
cobas e pack is displayed as empty E-254
Manual Registration window (e 601 module) E-255
Reagent Prime window E-256
Cassette Unloading window E-257
Test area E-257
Open Channel window E-258
Open Channel table E-258
Buttons E-258
Status screen E-259
Test list E-260
Reagent Details list E-261
Inventory list E-262
Buttons E-263
Inventory Setting window E-264
Confirmation window E-264

Setting screen

➔ **Reagent** > **Setting**

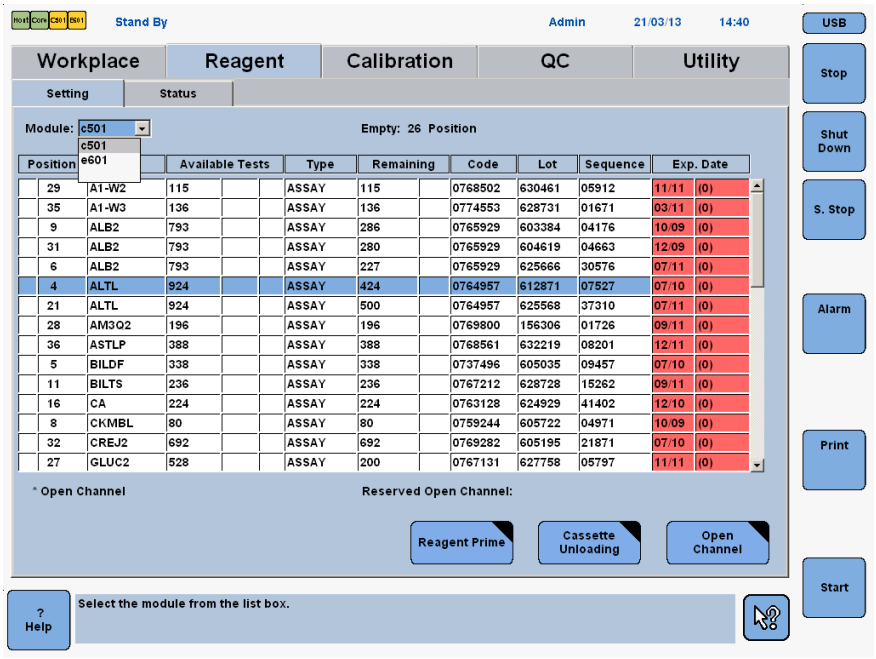


Figure E-158 Reagent > Setting screen

Use this screen to view details about reagents currently loaded on the modules, for example reagent lot information, on board stability or available tests. You can also use this screen to perform one of the following tasks:

- Load and unload reagents.
- For the **e** 601 you can manually register a reagent if the barcode was not registered by the system.
- You can also perform a reagent prime after reloading ISE reagents on the **c** 501.

For information, see:
Reagent Setting screen on page B-125
Manual reagent registration on page B-126
Loading and unloading of reagent cassettes (c 501) on page B-127
Reagent reloading (e 601) on page B-128
To replace ISE reference solution (ISE Ref.) on page B-47

Module list box Use this list box to select the module. Only reagents on the specified module are displayed in the setting screen list. Only one module can be selected at a time, not all.

Empty This field displays the number of unoccupied positions where **cobas c** packs or **cobas e** packs can be loaded.

Setting screen list

This list displays the reagent data for the reagents loaded on the selected module.

Position This column displays the positions of the reagent on the module.

The following symbols, which are displayed in the legend below the **Setting** screen list, may appear to the left of the position number:

*	Manual Setting An asterisk indicates manually registered reagents (**e** 601). An asterisk indicates manually registered reagents for development channel (**c** 501).
!	Barcode on manual registration An exclamation mark indicates manually registered information has been overwritten by information read from a barcode (**e** 601).
---	Occupied These symbols (---) indicate that a position is occupied but for which no information is available (**e** 601).

For more information on manually registered reagents, see *Manual reagent registration* on page B-126.

Test This column displays the short test name of the reagent currently loaded in the corresponding reagent position. Question marks appear in this column when a reagent barcode is registered by the barcode reader and the application parameters are not on the system (**e** 601). The test names can be highlighted to indicate user specific definable alarms.

The test names are highlighted to indicate alarms. The fields of the test list may be highlighted according to the following color code:

Red	A reagent is empty. The number of available tests is zero.
Yellow	The number of available tests for a reagent is below the check value defined under **Utility** > **System** (**Page 2/4**) > **Reagent Level Check**.
Purple	The number of available tests for a reagent is below the daily workload defined under **Utility** > **System** (**Page 2/4**) > **Reagent Level Check**. It is highlighted purple only, if the **Preventive Action** check box on the **System Overview** screen has been selected.

For more information, see:
Reagent Level Check window on page E-388
cobas e pack is displayed as empty on page E-254

Available Tests This column displays the total number of available tests on the selected module. If the number of available tests is zero, a red 0 is displayed.

If there are 2 numbers displayed in this column, the second number in brackets represents the level set for the **Purple Alarm** (**Utility** > **System** (**Page 2/4**) > **Reagent Level Check**). For example, 41(50): 41 tests are available, 50 tests are set as the **Purple Alarm** level.

See *Reagent Level Check window* on page E-388.

Type This column displays the type of reagent. The type of reagent depends on the module selected in the **Module** list box. The following table displays the available reagent types.

Module	Reagent	Description
c 501 (ISE)	IS	Internal standard solution
	DIL	Diluent
	KCL	Reference solution
c 501 (P)	ASSAY	Assay **cobas c** pack for photometric measurement
	DIL	Diluent **cobas c** pack
	D1	NaOH-D (ACN 947)
	D2	SMS (ACN 948)
	D3	SCCS (ACN 949)
e 601	ASSAY	Assay **cobas e** pack
	DIL	Diluent **cobas e** pack
	PRE	Pretreatment **cobas e** pack

Table E-10 Reagent types

Remaining This column displays the available amount of tests for this **cobas c** pack or **cobas e** pack in the corresponding reagent disk position.

Code This column displays the system ID of the **cobas c** pack or the application code number (ACN) of the **cobas e** pack in the corresponding position.

Lot This column displays the lot number of the reagent.

Sequence This column displays the sequence number of the **cobas c** pack or **cobas e** pack. It is printed as serial number on the barcode of the **cobas c** pack or **cobas e** pack. The sequence number is in combination with the lot number a unique number for this **cobas c** pack or **cobas e** pack. This way the system recognize if the **cobas c** pack or **cobas e** pack was on the system before.

Exp. Date This column displays two expiration dates:

- The first column displays the expiration date of the reagent in the corresponding position. If the reagent has already expired, this column is highlighted red.
- The second expiration date (number in brackets) displays the on board stability time (in days). The on board stability time is displayed in red if the on board stability time defined under **Utility** > **Application** > **Analyze** is exceeded.

Buttons

*Manual Registration (**e** 601)*

Choose this button to manually register a **cobas e** pack to the position currently selected in the list on the **Reagent** > **Setting** screen.

If the barcode of the **cobas e** packs is not readable, (---) is displayed in the **Test** column. Only then the button becomes active.

See *Manual Registration window (e 601 module)* on page E-255.

*Delete (**e** 601)*

Choose this button to delete the selected **cobas e** pack.

This button is only active for manually registered **cobas e** packs.

Reagent Prime

Choose this button to perform a reagent prime.

See *Reagent Prime window* on page E-256.

*Cassette Unloading (**c** 501)*

Choose this button to unload or dump a **cobas c** pack.

See *Cassette Unloading window* on page E-257.

Open Channel

Choose this button to reserve a Development Channel application to be assigned to a **cobas c** pack MULTI.

See *Open Channel window* on page E-258.

cobas e pack is displayed as empty

If a previously registered **cobas e** pack is placed back on an **e** 601 module, the liquid level of the microbeads is checked during Preparation and may not be found as expected. In this case the test of the corresponding **cobas e** pack is masked and it is displayed as empty in the **Reagent Setting** screen and the **Reagent Status** screen during Preparation and Operation.

Reagent Setting screen

Position	Test	Available Tests	Type	Remaining
1	TN-T	112	ASSAY	112
2	TSH	0	ASSAY	141

Reagent Status screen

Test Name	Available Tests
TN-T	112
TSH	0

In standby, the **Reagent Setting** screen and the **Reagent Status** screen display the remaining volume (**Available Tests**) of the test as is was displayed after the reagent registration.

However, the test will be masked again if you restart the system. The test can no longer be used on the **cobas** 6000 system. You have to replace the corresponding **cobas e** pack with a new one.

Manual Registration window (e 601 module)

➔ **Reagent** > **Setting** > **e** 601 > **Manual Registration**

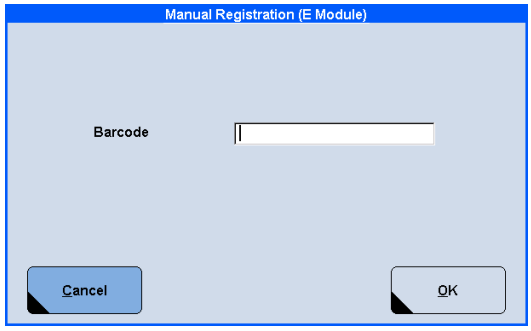


Figure E-159 Manual Registration window

Only if a barcode of a **cobas e** pack is not readable the **cobas e** pack can be manually registered by entering the 15 digit number on the side of the 2 dimensional barcode. If the barcode of the **cobas e** packs is not readable '---' is displayed in the **Reagent Setting** screen. Only then the button becomes active.

It is only possible to manually register a **cobas e** pack if at least one **cobas e** pack of the same lot was registered successfully before.

For more information on manual reagent registration, see *To manually register a cobas e pack* on page B-126.

Reagent Prime window

➔ **Reagent** > **Setting** > **Reagent Prime**

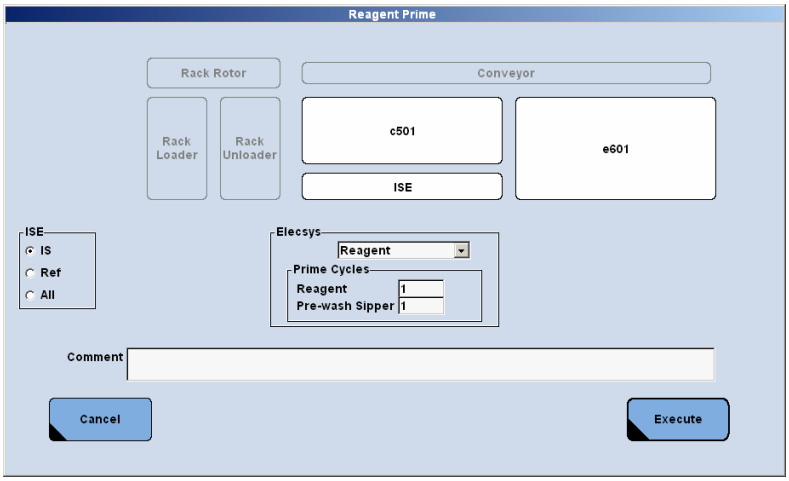


Figure E-160 Reagent Prime window

There are three ways to access this window.

- **System Overview** > **Reagent Prime** (**Work Flow** area)
- **Reagent** > **Setting** > **Reagent Prime**
- **Utility** > **Maintenance** > **Maintenance** (**Maintenance Type**) > **(8) Reagent Prime** > **Select**

For a complete description of this window, see *Reagent Prime window* on page E-431.

Cassette Unloading window

➔ **Reagent** > **Setting** > **Cassette Unloading**

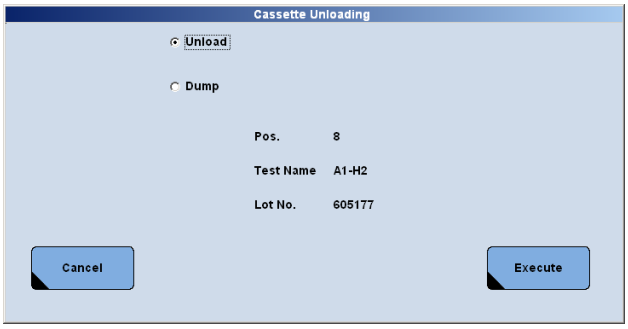


Figure E-161 Cassette Unloading window

Unload Select the **Unload** option to unload the **cobas c** pack from the **c** 501 module in case you want to continue using it.

Dump Select the **Dump** option to discard the **cobas c** pack. You cannot register it on the system again.

If you use the option **Dump** for unloading a cassette, the cassette cannot be reloaded on this system.

Test area

Pos. This field displays the position of the **cobas c** pack in the module.

Test Name This field displays the short test name of the reagent.

Lot No. This field displays the lot number of the reagent.

Open Channel window

➔ **Reagent** > **Setting** > **Open Channel**

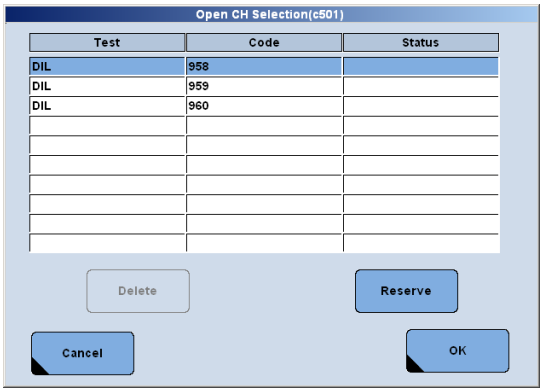


Figure E-162 Open CH Selection (**c** 501) window

This window is used to assign a **cobas c** pack MULTI to an already installed development channel application (open channel). The development channel must be installed before loading the corresponding **cobas c** pack MULTI.

Please contact your Roche service representative for more information.

Open Channel table

The table displays test and diluent information of the development channel applications installed on the **c** 501 module.

Test The **Test** column displays the name of the test or **DIL** for diluents.

Code The **Code** column displays the application code of the test or the diluent.

Status The **Status** column displays the status of the development channel application:

- **Reserved**

 If you choose the **Reserve** button the selected test is reserved for the next **cobas c** pack MULTI that is loaded on the **c** 501 module.

- **Assigned**

 If a **cobas c** pack MULTI is loaded, it is assigned to the reserved test.

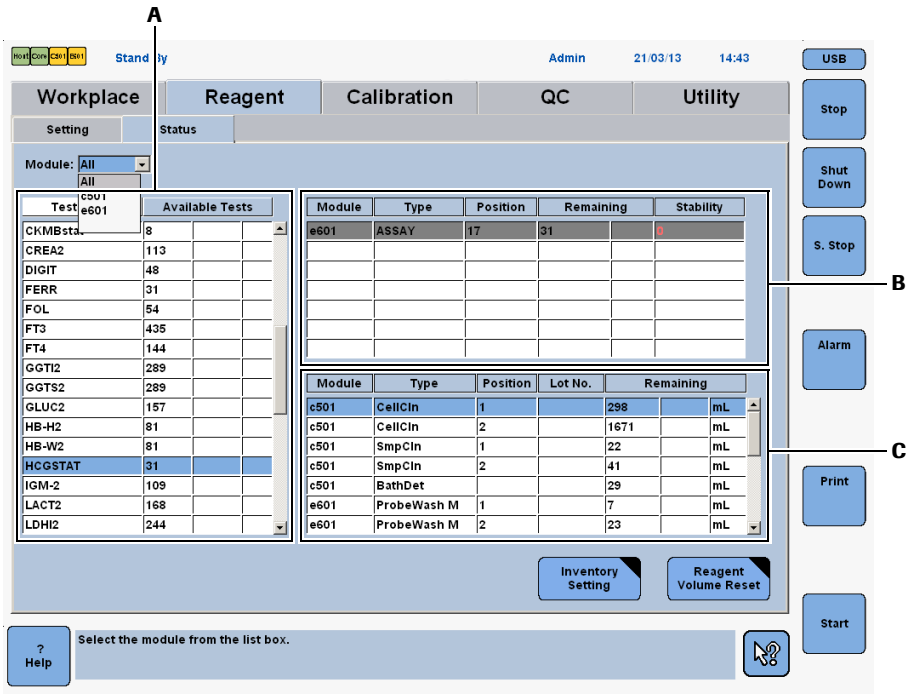
Buttons

Reserve Choose this button to reserve a test. If you then load a **cobas c** pack MULTI, it is assigned to the reserved test.

Delete Choose this button to cancel a development channel reservation.

Status screen

➔ **Reagent** > **Status**



A Test list
B Reagent Detail list
C Inventory list

Figure E-163 Reagent > Status screen

Use the **Reagent Status** screen to view the status of the reagents loaded on the system. The inventory of the modules can also be viewed from this screen.

For more information, see:
Reagent Status screen on page B-130
Replacing auxiliary reagents (c 501) on page B-131
Replacing auxiliary reagents (e 601) on page B-132

This screen consists of 3 lists:

- The *Test list* on the left side displays every test.
- The *Reagent Detail list* on the top of the right side displays reagent details of the test currently selected in the test list.
- The *Inventory list* on the bottom of the right side displays the status of the inventory.

Module list box Use this list box to select one module or all modules. Only reagents on the specified module are displayed in the test list on the left.

Test list

Use this list, on the left of the **Reagent** > **Status** screen, to select a test of which the details are to be displayed on the reagent details list on the right. The test list can be sorted by the test name or by the number of available tests. A white background shows which sorting function is activated.

Test Name

This column displays the short test name of the reagent currently loaded in the corresponding reagent position. The test names can be highlighted to indicate user specific definable alarms.

If question marks (?????) are displayed, the corresponding test is not assigned to a module. Or the application for the corresponding reagent is not installed (e 601).

The test names are highlighted to indicate alarms. The fields of the test list may be highlighted according to the following color code:

Red	A reagent is empty. The number of available tests is zero.
Yellow	The number of available tests for a reagent is below the check value defined under **Utility** > **System** (**Page 2/4**) > **Reagent Level Check**.
Purple	The number of available tests for a reagent is below the daily workload defined under **Utility** > **System** (**Page 2/4**) > **Reagent Level Check**. It is highlighted purple only, if the **Preventive Action** check box on the **System Overview** screen has been selected.

For more information, see:
Reagent Level Check window on page E-388
cobas e pack is displayed as empty on page E-254

Available Tests

This column displays the total number of available tests on the selected module. If the number of available tests is zero, a red 0 is displayed.

If there are 2 numbers displayed in this column, the second number in brackets represents the level set for the **Purple Alarm** (**Utility** > **System** (**Page 2/4**) > **Reagent Level Check**). For example, 41(50): 41 tests are available, 50 tests are set as the **Purple Alarm** level.

See *Reagent Level Check window* on page E-388.

Reagent Details list

Use this list, on the top right of the **Reagent** > **Status** screen, to view details of the reagents loaded on the modules. The displayed details correspond to the test currently selected in the test list on the left.

Module This column displays the module on which the reagent is loaded.

Type This column displays the type of reagent. The type of reagent depends on the module selected in the **Module** list box. The following table displays the available reagent types.

Module	Reagent	Description
c 501 (ISE)	IS	Internal standard solution
	DIL	Diluent
	KCL	Reference solution
c 501 (P)	ASSAY	Assay **cobas c** pack for photometric measurement
	DIL	Diluent **cobas c** pack
	D1	NaOH-D (ACN 947)
	D2	SMS (ACN 948)
	D3	SCCS (ACN 949)
e 601	ASSAY	Assay **cobas e** pack
	DIL	Diluent **cobas e** pack
	PRE	Pretreatment **cobas e** pack

Table E-11 Reagent types

Position This column displays the position on the module.

Remaining Depending on the reagent type this column displays the following information:

- If a diluent or a detergent is selected, the remaining volume is displayed.
- If a reagent is selected, the number of tests remaining is displayed.

Stability This column displays two items for the **cobas c** pack or **cobas e** pack:

- The expiration date of the reagent lot. If it is expired, the background of this field is red.
- The on board stability of the **cobas c** pack or **cobas e** pack. If the on board stability is expired, the numbers in this column are displayed in red.

Inventory list

Use this list, on the bottom right of the **Reagent** > **Status** screen, to view the auxiliary reagents, solid consumables and waste levels of the selected module in the **Module** list box.

Module This column displays the module on which the system consumables are loaded.

Type This column displays the type of auxiliary reagent and consumable. The following colors are possible:

c 501 auxiliary reagents	Unit	Color	Description
CellCln 1/CellCln 2	ml	Purple	Volume < purple alarm level
(Cell Wash Solution I / NaOH-D and Cell wash Solution II / Acid Wash)		Yellow	Volume ≤ 50 ml
		Red	Bottle empty
SmpCln 1/SmpCln 2	ml	Purple	Volume < purple alarm level
(Sample Cleaner 1 and Sample Cleaner 2)		Yellow	Volume < yellow alarm level
		Red	Bottle empty
BathDet	ml	Purple	Volume < purple alarm level
(EcoTergent)		Yellow	Volume < yellow alarm level
		Red	Bottle empty

Table E-12 **c** 501 module auxiliary reagent types

For information on reagent level check alarm settings, see *Reagent Level Check window* on page E-388.

e 601 auxiliary reagents	Unit	Color	Description
ProbeWash M 1/2	%	Yellow	One bottle empty
(ProbeWash bottle 1 and 2)		Red	Both bottles empty
ProCell 1/2	%	Yellow	One bottle empty
(ProCell bottle 1 and 2)		Red	Both bottles empty
CleanCell 1/2	%	Yellow	One bottle empty
(CleanCell bottle 1 and 2)		Red	Both bottles empty
PreClean M 1/2	%	Yellow	One bottle empty
(PreClean bottle 1 and 2)		Red	Both bottles empty

Table E-13 **e** 601 module auxiliary reagent types

e 601 magazine and waste	Unit	Color	Description
Magazine (Magazine with assay tips and assay cups)	Number (max 12)	Yellow	One magazine remaining
		Red	No magazines remaining (One blue box means one available magazine)
MagWaste (Empty magazine)	Number (max 12)	Yellow	Space for one empty magazine remaining
		Red	No space for empty magazines remaining
SolidWaste 1/2 (Solid waste for assay tips and assay cups)		Yellow	One solid waste remaining
		Red	No solid waste remaining

Table E-14 **e** 601 module magazine and waste types

Position This column displays the position of the auxiliary reagent or the solid waste container (**e** 601 only) on the module.

Lot No. This column displays the auxiliary reagent lot number of ProCell, if it was manually entered (**e** 601 only).

Remaining This column displays the amount of the consumable remaining, expressed in ml or number of items.

If **Preventive Action** on the **System Overview** screen is checked the remaining volume is displayed with the purple alarm value that has been set in **Utility** > **System** (**Page 2/4**) > **Reagent Level Check** (**c** 501 only).

See *Reagent Level Check window* on page E-388.

Buttons

*Inventory Setting (**e** 601)* Choose this button to display the **Inventory Set** window. Use this window to enter the ProCell lot number.

See *Inventory Setting window* on page E-264.

*Reagent Volume Reset (**c** 501)* Choose this button to display the **Confirmation** window. Use this window to reset the remaining volume of detergents for the **c** 501. The volume can only be reset in standby.

See *Confirmation window* on page E-264.

Only reset the reagent volume count in the software after a new reagent bottle has been placed.

Inventory Setting window

➔ **Reagent** > **Status** > **e** 601 (**Module** list box) > **Inventory Setting**

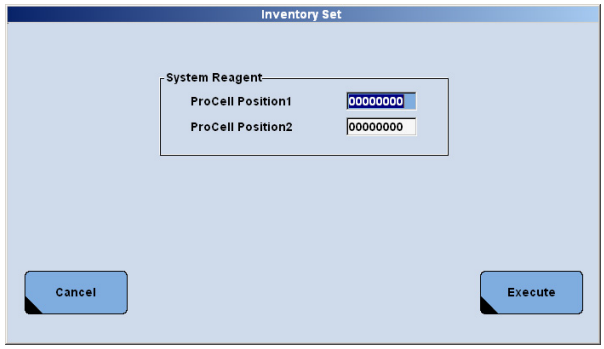


Figure E-164 Inventory Setting window

Use this window to specify the lot number for ProCell on the **e** 601.

System Reagent area This area specifies the two different ProCell positions on the **e** 601.

ProCell Position1/2 Use this text boxes to enter the ProCell lot number used on the two different positions.

Confirmation window

➔ **Reagent** > **Status** > **c** 501 (**Module** list box) > **Reagent Volume Reset**

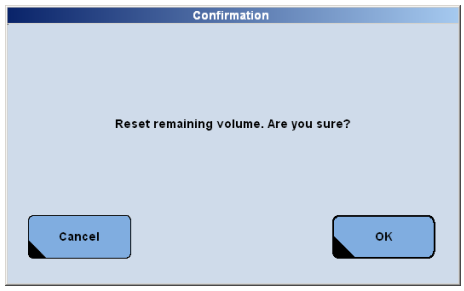


Figure E-165 Confirmation window

Use this window to reset the remaining volume of detergents for **c** 501. The volume can only be reset in standby.

The button is only active if a **c** 501 module is selected or **ALL**.

Calibration menu

This chapter provides a detailed description of the **Calibration** menu and the windows accessed from it. In the **Calibration** menu you can see which tests require a calibration. You can also review or validate a calibration and compare the current calibration with previous ones.

In this chapter *Chapter* 25

Status screen E-267
Status list E-268
Method area E-269
Buttons E-270
Calibration Trace window E-271
Graph area E-274
Buttons E-274
Scale Setting window – Calibration Trace E-275
Comment window – Calibration Trace E-276
Calibration Result (ISE) window E-277
Calibration Result (Photometry) window E-279
Calibration result table E-279
Definition text boxes E-280
Buttons E-281
Calibration Result (Immune) window E-282
Calibration result table E-283
Working Information window (c 501) E-284
Button E-285
Scale Setting window – Working Information E-286
Calibration Factor window (c 501) E-287
Reaction Monitor window (c 501) E-289
Graph area E-290
Buttons E-290
Scale Setting window – Reaction Monitor E-291
Instrument Factor window E-292
Factors list E-292
Y = aX + b area E-293
Start Up Setting window E-294
Start Up list E-295

Method area E-295
Calibrator screen E-296
Calibrator list E-297
Buttons E-297
Calibrator Rack Assignment window E-298
Calibrator list E-299
Position list E-299
Buttons E-299
Install screen E-300
Calibrator list E-301
Test list E-301
Buttons E-301
Assignment window E-302
Download window E-303
Search Using area E-303
Sort By area E-304
Download area E-304
Confirmation window (calibrator download) E-305
Message area E-305
Registration Parameters area E-305
Download Parameters area E-306
Edit Calibrator window (c 501 only) E-307
Test list E-308
Std Concentration area E-308

Status screen

➔ **Calibration** > **Status**

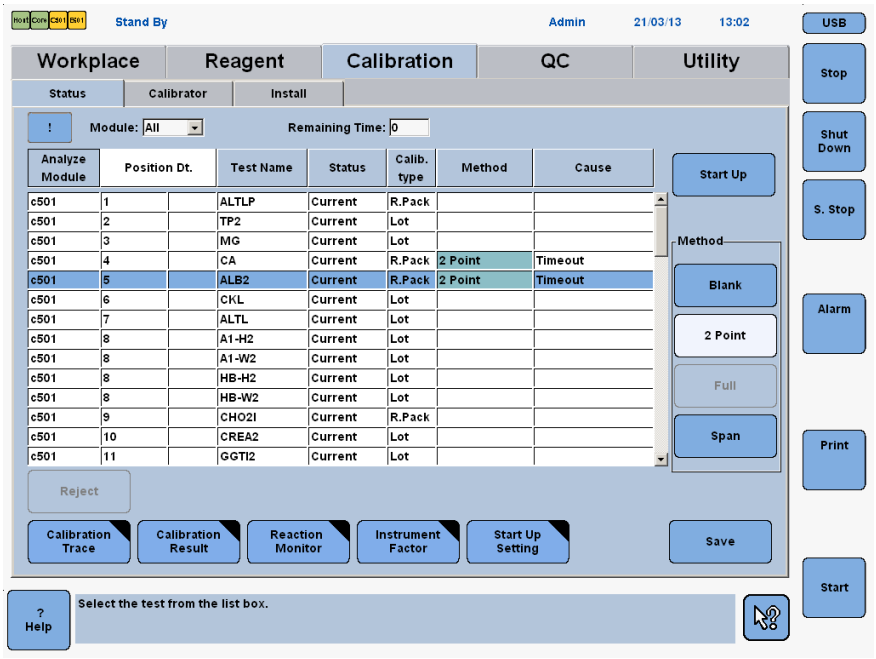


Figure E-166 Status screen

The **Calibration Status** screen displays if a test is recommended by the system or manually selected for start up, timeout, repeat, changeover or manual calibrations.

For detailed information on calibration operations, see:
Calibration and QC Select button on page B-51
Calibration concept on page B-155
Reviewing calibration data on page B-169
Calibration factors (c 501) on page B-176

The timeout period for an assay is automatically reset when a successful calibration is performed. The timeout period for an assay is not reset when a calibration fails.

If automatic calibration masking is activated, the corresponding test with the Failed calibration data is masked. No more results are reported for this test. If automatic calibration masking is **OFF**, the last successful calibration is applied for sample results.

See *Calibration Mask Setting window* on page E-392.

Exclamation Point button This button turns yellow if the displayed status list should be updated. The displayed information may be out-of-date, for example, if a calibration has been performed in the meantime. Choose the Exclamation Point to update the status list.

Module Use this list box to select the module or all modules, whose tests are to be displayed in the test list.

Remaining Time This text box is used to set the timeout criteria (0-9999 hours). Any test of which the calibration fulfills the timeout criteria within this time period is recommended for a timeout calibration. The test is automatically highlighted gray in the **Method** column if **Preventive Action** is activated. The cause **Calib. Now** is displayed in the **Cause** column.

See *Preventive action* on page B-40.

Status list

The status list in the center of the screen consists of 7 columns. It can be sorted by test position, test name, calibration type, calibration method or cause by choosing the appropriate tab (column header). A white background indicates which sorting function is selected.

Missing test

If a test is not listed in the status list, check if the corresponding **cobas c** pack or **cobas e** pack is on board.

Analyze Module This column specified the module to which this calibration information refers to.

Position Dt. This column is divided into two sub-columns.

The left column displays the reagent position on the instrument.

The right column displays:

- For **e** 601 the measuring channel on which the calibration was performed.
- For ISE it displays the calibration curve used for calibration (A or B).

For information about the ISE calibration curves, see:
Calibration concept - ISE applications on page B-159
Sample type specific ISE calibration curves on page B-159
ISE calibration on page B-193

Test Name This column displays the short test name.

Status This column displays if it is a current or standby reagent. Currently used reagents are indicated by Current, standby reagents are indicated by SB1, SB2, …SBn.

Calib. Type This column displays whether a calibration is a lot calibration (**Lot**) or a reagent pack calibration (**R.Pack**). There is no indication (blank space) for ISE calibration.

For requested calibrations (highlighted in green), the entry under **Calib. Type** refers to the upcoming calibration if a valid calibration is generated. Otherwise the entry under **Calib. Type** refers to the existing calibration.

For more information, see:
Lot and cassette calibrations for cobas c packs on page B-161
Lot and cassette calibrations for cobas e packs on page B-163

Method This column displays the calibration method selected.

If this field is displayed with a gray background, the calibration is recommended by the system. To accept the recommendation press the **Save** button. If this field is displayed with a green background, a calibration is requested. This might be by accepting the recommendation or by manually requesting a calibration.

Cause This column displays the reason why the calibration is recommended or requested. Possible reasons include **Calib. Now**, **Changeover**, **Timeout**, **QC Violation**, **Manual** and **Failed**.

Calib. Now	When the test times out during the specified period of time in the **Remaining Time** box; displayed only if **Preventive Action** is activated
Changeover	When a new test or a new lot is loaded on the system.
Failed	When a calibration is failed, it needs to be repeated.
Manual	When calibration is manually requested by the operator.
QC Violation	If the test is configured for QC-triggered calibration and a QC result is out of the specified confidence range. The configuration is defined on **Utility** > **Application** > **Calib.**
Timeout	When the timeout period of the reagent is exceeded.

Method area

The **Method** area contains 4 buttons for selecting the calibration method: **Blank**, **2 Point**, **Full**, and **Span**.

For **e** 601, only **Full** is available.

For **c** 501, if **Full** is available as calibration method choose **Full** (e.g. for ISE).

For more information, see *Calibration methods* on page B-160.

Blank Select this button to choose a blank calibration.

2 Point Select this button to choose a 2 Point calibration.

Full Select this button to choose a full calibration. If available always select this calibration method.

Span Select this button to choose a span calibration.

Buttons

Start Up Use this button to select tests for calibration which are defined on the **Calibration** > **Start Up Setting** window.

See *Start Up Setting window* on page E-294.

Reject Use this button to reject a failed calibration. This button is only available if the last calibration for this test was a failed calibration.

When a calibration fails, *Failed* is displayed in the **Cause** column.

- If auto masking is activated, no control or patient sample can be measured with this reagent. Using the **Reject** button, in this case, unmasks the test; results are calculated with the previous calibration curve and no **Cal.E** alarm is attached to the results.
- If auto masking is not activated, controls and patient samples are measured but the results are calculated with the previous calibration curve and a **Cal.E** alarm is attached to the results. Using the **Reject** button, in this case, deletes the calibration recommendation and no **Cal.E** alarm is attached to the results.

Calibration Trace Choose this button to display the **Calibration Trace** window. This window shows the absorbance values or signal values of the 50 most recent calibrations data for a specific test.

For more information, see:
Calibration Trace window on page E-271
Calibration Result (ISE) window on page E-277
Calibration Result (Photometry) window on page E-279
Calibration Result (Immune) window on page E-282

Calibration Result Choose this button to display the **Calibration Result** window. This window shows the results for the most recent calibration for the selected test. This window is different depending on the module, on which the test is performed.

For more information, see:
Calibration Result (ISE) window on page E-277
Calibration Result (Photometry) window on page E-279
Calibration Result (Immune) window on page E-282

Reaction Monitor Choose this button to display the **Reaction Monitor** window. Use this window to view the reaction curve of the calibration selected in the status list (**c** 501 only).

See *Reaction Monitor window (c 501)* on page E-289.

Instrument Factor Choose this button to display the **Instrument Factor** window. The default settings are: Factor a 1.0, Factor b 0.0.

The default settings should not be changed for **e** 601.

See *Instrument Factor window* on page E-292.

Start Up Setting Choose this button to display the **Start Up Setting** window. Use this window to define tests for a start up calibration.

See *Start Up Setting window* on page E-294.

Calibration Trace window

➔ **Calibration** > **Status** > **Calibration Trace**

This window is used to review the absorbance values of the 50 most recent calibrations for a specific test.

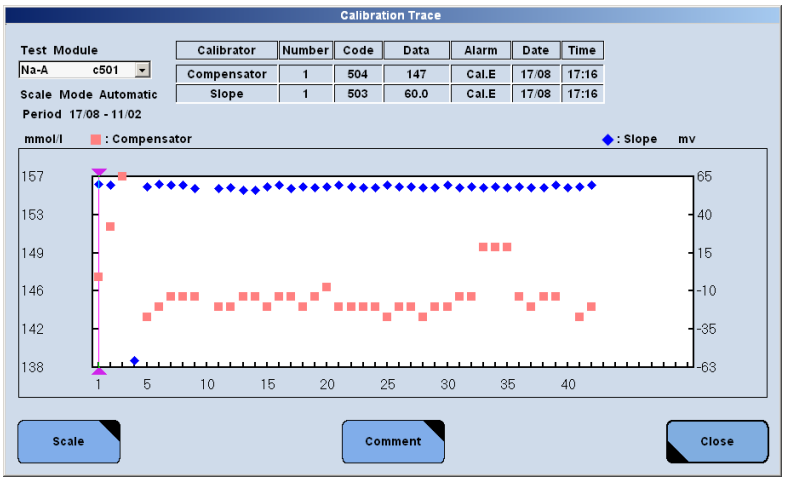


Figure E-167 Calibration Trace window for ISE calibrations

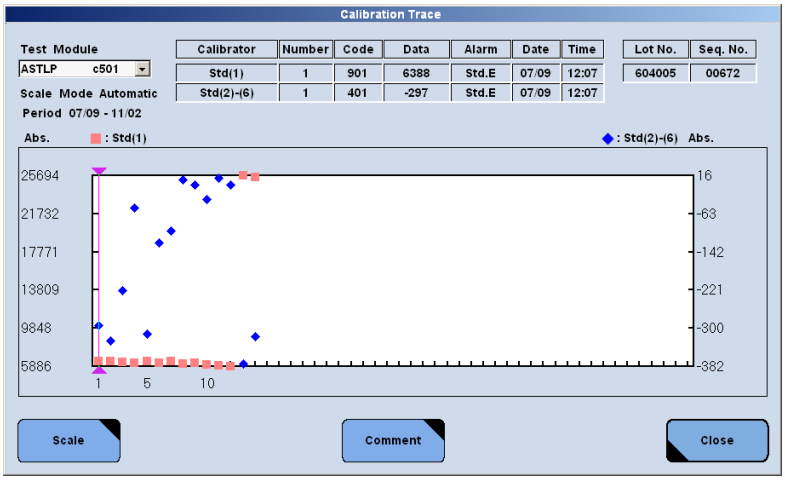


Figure E-168 Calibration Trace window for photometric calibrations **c** 501

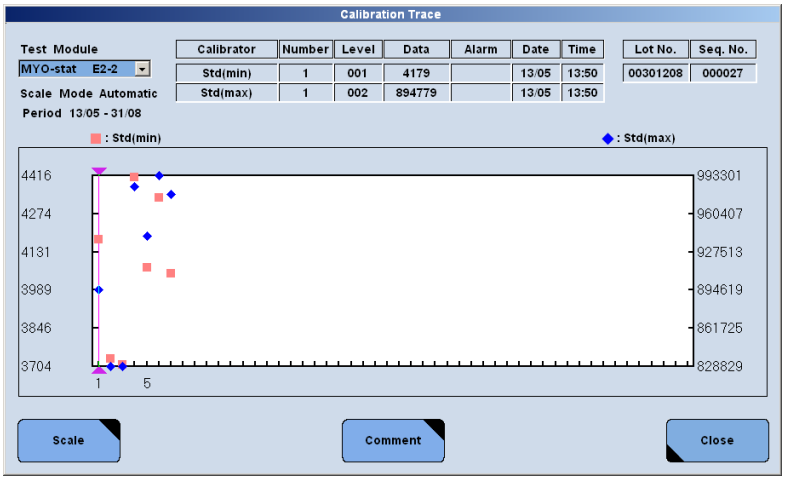


Figure E-169 Calibration Trace window for calibrations **e** 601

The calibration data is plotted on the X-axis by date, with the oldest calibration beginning at the left.

The left and right Y-axes are scaled independently. They can be scaled automatically or manually using the **Scale Setting** window.

For more information, see:
Graph area on page E-274
Scale Setting window – Calibration Trace on page E-275
Checking calibrations of photometric tests on page B-169
Checking calibrations of ISE tests on page B-173
Checking calibrations of e 601 tests on page B-174

Test Module This list box displays the test and module combination selected in the status list on the **Status** screen. For **e** 601 tests, the measuring channel is also displayed (for example E-1). If you select a different test and module combination from this list box, the data in this window reflect the information for the combination selected.

Calibrator This column displays the calibrator type for the selected calibration, either **Compensator** (ISE Std 3) and **Slope** (ISE), **Std1** and **Std (2)**-**(6)** (**c** 501), or **Std (min)** and **Std (max)** (**e** 601).

Number This column displays the number (1 to 50) of the selected calibration in the calibration trace.

*Level (**e** 601)* This column displays the two level used in the calibration.

*Code (**c** 501, P and ISE)* This column displays the code for the calibrator codes used for this calibration.

Data This column displays the data for the selected calibration, i.e., the signal values for **e** 601 or the absorbance for **c** 501 (P), or the concentration and mV values for **c** 501 (ISE).

Alarm For **c** 501, this column displays the alarm code for the selected calibration, if applicable. An asterisk (*) is displayed in case the **Update Type** (**Calibration Type** area on **Utility** > **Application** > **Calib**.) is set to **Difference** or **Ratio** and the calibration was not measured with the **Full** method.

For **e** 601, an asterisk (*) is displayed if a calibration quality criteria is failed. If a R.Pack calibration is failed because of the factor (<0.8 or >1.2) then the failed calibration is not indicated.

See *Calibration quality criteria for immunological applications* on page B-164.

Date This column displays the date when the selected calibration was performed.

Time This column displays the time when the selected calibration was performed (calibration result time).

Lot No. This field displays the lot number of the **cobas c** pack or **cobas e** pack used to perform the selected calibration.

Seq. No. This field displays the sequence number of the **cobas c** pack or **cobas e** pack used for the selected calibration.

Scale Mode This field displays the scale, **Automatic** or **Manual**, selected on the **Scale Setting** window.

See *Scale Setting window – Calibration Trace* on page E-275.

Period This field displays the date range represented by the calibration points in the graph area.

Graph area

The graph area shows different information depending on the selected test (photometric, ISE, immunological).

The left and right Y-axes are scaled independently. They can be scaled automatically or manually using the **Scale Setting** window.

See *Scale Setting window – Calibration Trace* on page E-275.

***c** 501 (P)* The graph shows calibration results for the selected photometric test. It displays the measured absorbance values for both the Std (1) calibrator and the calibrator with the maximum concentration Std (2)-Std (6) on one plot.

The left and right Y-axes are scaled independently:

- The left axis refers to the Std (1) calibrator represented by ■.

 In case of a multipoint calibration, the absorbance value of the highest calibrator is shown.

 In case of a rate assay, it indicates the primary wavelength absorbance at photometric measuring point 1 of Std (1).
- The right axis refers to the maximum calibrator Std (2)-Std (6) represented by ◆.

***c** 501 (ISE)* The graph shows calibration results for the selected ISE test. The left and right Y-axes are scaled independently:

- The left axis refers to the measured concentration values of the ISE Standard 3 represented by ■.
- The right axis refers to the calculated slope values represented by ◆.

***e** 601* The graph shows calibration data for the selected test; it displays the measured signal values for both the low concentration calibrator, Std (min), and the high concentration calibrator, Std (max), on one plot.

The left and right Y-axes are scaled independently:

- The left axis refers to the Std (min) calibrator, represented by ■. Std (min) represents Cal 1.
- The right axis refers to the Std (max) calibrator, represented by ◆. Std (max) represents Cal 2.

Buttons

Scale Choose this button to display the **Scale Setting** window. This window is used to set the scale of the calibration trace.

See *Scale Setting window – Calibration Trace* on page E-275.

Comment Choose this button to display the **Comment** window.

This window is used to enter a comment. If a comment for the selected calibration exists, this button is yellow.

See *Comment window – Calibration Trace* on page E-276.

Scale Setting window – Calibration Trace

➔ **Calibration** > **Status** > **Calibration Trace** > **Scale**

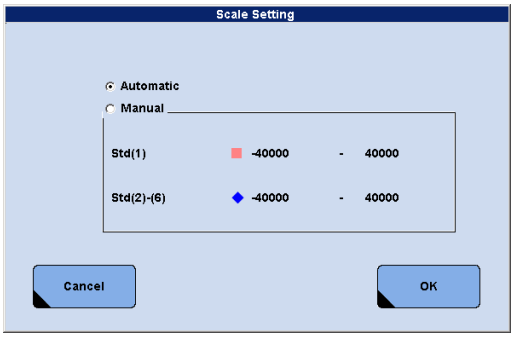


Figure E-170 Scale Setting window

This window is used to define the scaling for the graphics display in the **Calibration Trace** window.

You may define separate manual scaling factors for both Y-axes.

- The values of the left axis are represented by ■.
- The values of the right axis are represented by ◆.

Another option is to select the **Automatic** scaling by the system.

Automatic Select this option to display the calibration trace automatically adjusted by the system. In this case, the system determines the appropriate scale setting necessary to display the calibration values.

Manual For all tests, except for ISE, you can enter values for the lower and upper limits. For **c** 501 the values stand for absorbance values, for **e** 601 the values stand for signal values.

Comment window – Calibration Trace

➔ **Calibration** > **Status** > **Calibration Trace** > **Comment**



Figure E-171 Comment window

Use this window to enter a comment of up to 600 characters for the selected calibration. These comments will be printed on the **Calibration Trace** report.

See *Calibration Trace* on page E-111.

OK Choose **OK** to accept and save the entry.

Cancel Choose **Cancel** to close the window without saving any entries.

Calibration Result (ISE) window

➔ **Calibration** > **Status** > **Calibration Result**

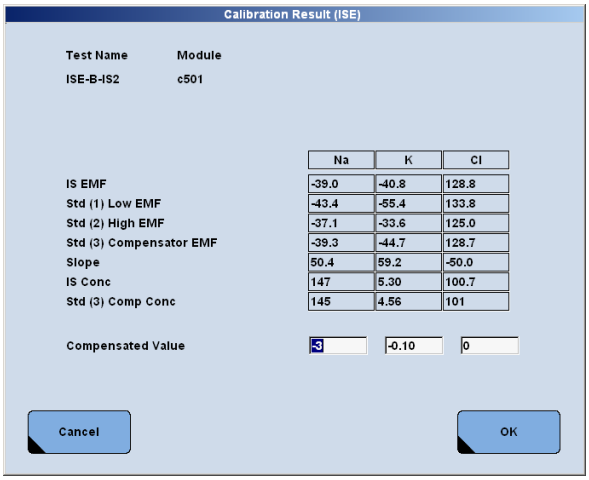


Figure E-172 Calibration Result (ISE) window

Use this window to display the results from the most recent successful calibration for the selected ISE test in the status list on the **Calibration** > **Status** screen.

To edit the compensated values, a supervisor level (or higher) is necessary.

It is not recommended to change the compensated values.

Test Name This field displays the ISE calibration curve selected in the **Status** list on the **Calibration** > **Status** screen. **ISE-A-IS1** means calibration curve A, calibrated with internal standard bottle 1.

For more information, see:
Calibration concept - ISE applications on page B-159
ISE Calibration Setting window on page E-411
Other (c 501 ISE tests) on page E-510

Module This field displays the module **c** 501 (ISE) used to perform the calibration, e.g. C1 or C2.

IS EMF This field displays the electrical potential (electromotive force) of the internal standard solution in millivolts (mV) for Na^+, K^+ and Cl^-.

Std (1) Low EMF This field displays the electrical potential (electromotive force) of ISE Standard 1 (ISE Low) for Na^+, K^+ and Cl^-.

Std (2) High EMF This field displays the electrical potential (electromotive force) of ISE Standard 2 (ISE High) for Na^+, K^+ and Cl^-.

Std (3) Compensator EMF This field displays the electrical potential (electromotive force) of ISE Standard 3 (ISE High) for Na^+, K^+ and Cl^-.

Slope This field displays the response (millivolts/decade) of each electrode cartridge for Na^+, K^+ and Cl^-.

IS Conc This field displays the concentration of the internal reference solution as determined during calibration for Na^+, K^+ and Cl^-.

Std (3) Comp Conc This field displays the measured concentration of the ISE Standard 3 (ISE High) as determined during calibration for Na^+, K^+ and Cl^-.

Compensated Value This field displays the difference between the target value of the ISE Standard 3 (ISE High) and its measured concentration for Na^+, K^+ and Cl^-. The compensated value can range from -99999 to 999999. The difference is added to all measured controls and patients samples.



It is not recommended that you change the compensated values. However, for research or special investigative studies, the compensated values may be changed provided that the ISE unit is fully recalibrated before measuring and reporting control and patient results.

Calibration Result (Photometry) window

➔ **Calibration** > **Status** > **Calibration Result**

This window can be viewed on any password level. To edit the data a supervisor level (or higher) is necessary.

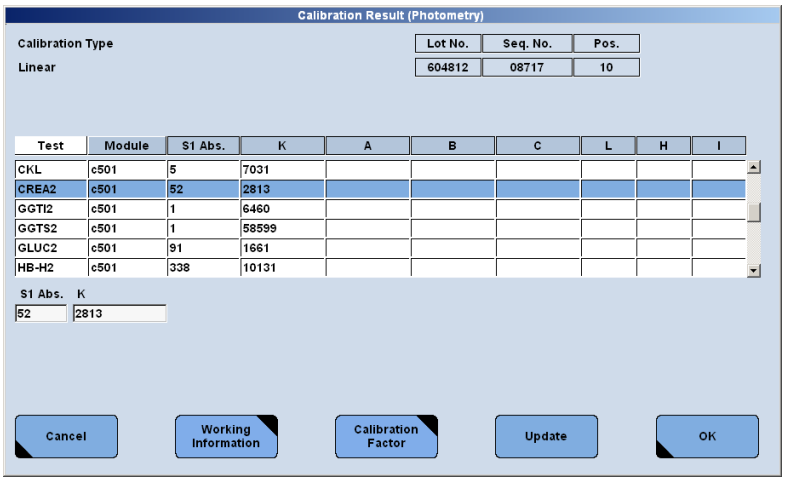


Figure E-173 Calibration Result (Photometry) window

The **Calibration Result** window displays a summary of calibration information for all **c** 501 (P) tests available on the system.

Calibration Type This field displays the calibration curve type for the selected test. The calibration method is programmed on the **Utility** > **Application** > **Calib.** window. The options are: **Linear**, **Spline**, **Line Graph, RCM**, **RCM2T1**, and **RCM2T2**.

See *Types of calibration curves* on page B-160.

Lot No. This field displays the lot number of the calibrator used for the currently selected calibration.

Seq. No. This field displays the ID bottle number of the reagent used for the currently selected calibration.

Pos. This field displays the position where the **cobas c** pack is located.

Calibration result table

The calibration result list can be sorted by **Test** or **Module** by choosing the appropriate tab (column header).

Test The **Test** column displays the short name of the photometric (**c** 501) tests available on the system.

Module The **Module** column displays the **c** 501, to which the test is assigned, e. g. C1 or C2.

S1 Abs. The **S1 Abs.** column displays the absorbance of calibrator (1). This number can be changed by using the **S1 Abs.** text box below.

K The **K** column displays the reciprocal value of the slope of the calibration curve (K factor). This number can be changed by using the **K** text box below.

A The **A** column displays the nonlinear coefficient A (slope). This number can be changed by using the **A** text box below.

B The **B** column displays the nonlinear coefficient B (intercept). This number can be changed by using the **B** text box below this list.

C The **C** column displays the nonlinear coefficient C (cubic spline exponential). This number can be changed by using the **C** text box below this list.

L The **L** column displays the bichromatic absorbance difference of the lipemia serum index. This figure can be updated using the **L** text box below this list.

H The **H** column displays the bichromatic absorbance difference of the hemolysis index. This figure can be updated using the **H** text box below this list.

I The **I** column displays the bichromatic absorbance difference of the icterus index. This figure can be updated using the **I** text box below this list.

Definition text boxes

S1 Abs Use this text box under the **Calibration Result** list to define the values of the S1 absorbance. The entry is displayed in the **Calibration Result** list. Edit the value in the text box and choose **Update** to change the value.

K Use this text box under the **Calibration Result** list to define the coefficients. The entry is displayed in the **Calibration Result** list. Edit the value in the text box and choose **Update** to change the value.

A, B, C, L, H, I Use this text boxes under the **Calibration Result** list to define the coefficients. The entry is displayed in the **Calibration Result** list. Edit the value in the text box and choose **Update** to change the value.



These text boxes are displayed only when a value is displayed for the selected test in the Calibration Result list.

Buttons

Working Information Choose this button to display the **Working Information** window. This window is used to display the calibration curve for the selected calibration in the **Calibration Result** list.

For more information, see *Working Information window (c 501)* on page E-284.

Calibration Factor Choose this button to display the **Calibration Factor** window. This window is used to display the coefficients K, A, and B for the selected calibration in the **Calibration Result** list.

For more information, see *Calibration Factor window (c 501)* on page E-287.

Update Choose this button to update the **Calibration Result** list with the changes made in the definition text boxes. This button is yellow if a change has been made but not updated.

Calibration Result (Immune) window

➔ **Calibration** > **Status** > **Calibration Result**

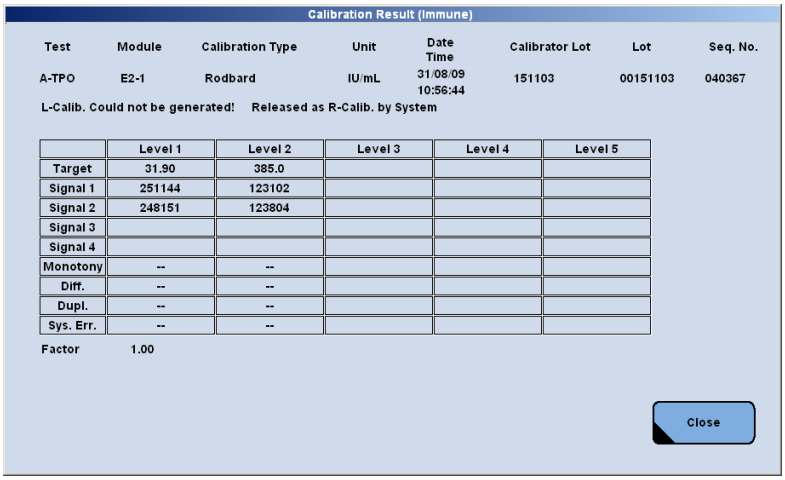


Figure E-174 Calibration Result (Immune) window.

This window differs depending on the type of calibration performed (qualitative or quantitative).

Use this window to view the results from the most recent calibration for the selected test in the status list on the **Calibration** > **Status** screen.

Test This column displays the report test name.

Module This field displays the name of the module and the measuring channel.

Calibration Type This field displays the calibration curve type. The calibration type is either **Rodbard** for quantitative assays, or **Cutoff** for qualitative assays.

Unit This column displays the unit of measure for each test as defined on the **Utility** > **Application** screen.

Date Time This field displays the date and time when the calibration was performed.

Calibrator Lot This column displays the lot number of the calibrator used.

Lot This column displays the lot number of the **cobas e** pack used for the calibration.

Seq. No. This column displays the sequence number of the **cobas e** pack used for the calibration.

Status Messages One of the following messages will be displayed:

- *L-Calib was generated* (means: **cobas e** pack was calibrated within 24 hours on board)
- *L-Calib could not be generated. Released as R-Pack Calib.* (means: **cobas e** pack was calibrated after 24 hours on board)
- *L-Calib could not be generated. Calib. with expired Rack Pack.* (means: no matter how long on board—with expired reagent only R-Pack Calib. can be generated.)
- *L-Calib could not be generated.* (means: failed calibration, no matter how long on board).

Calibration result table

This table displays calibration details, including some calibration quality criteria for the calibration performed.

For further information about the calibration quality criteria, refer to the COBI CD.

Level The columns Level 1 and Level 2 display the information for calibrator level 1 and calibrator level 2.

Target The target value of the calibrator. The target values are displayed only after the calibration is completed.

Signal 1 / Signal 2 The result of the first and the second measurement of the corresponding calibrator level.

- <Sig: The calibrator signal is lower than the specified lower limit value.
- >Sig: The calibrator signal is higher than the specified upper limit value.
- NG: No calibrator signal was detected by the measuring cell.

Flags for Monotony, Diff., Dupl., and SysErr For *Monotony*, *Diff.*, *Dupl.*, and *SysErr* the following flags are displayed:

- If the criterion is met, -- is displayed.
- If the criterion is not met, *NG* is displayed.

Monotony All measured calibrator values must fall in ascending or descending order.

Diff. Defined as the difference in percent of the signal level values between calibrator 1 and 2. This difference must amount to at least 30% for the calibration to be accepted.

Dupl. The deviation of duplicate measurements is a check of the signal values for each replicate of a calibrator. If the difference between the duplicate measurements is above a certain limit, the calibration fails.

Sys. Err. A hardware error occurred during the measurement.

Factor The factor of a lot calibration (L-Calib.) is 1.00. The factor of a reagent pack calibration (R-Calib.) must lie between 0.8-1.2. Otherwise, the calibration is failed and the corresponding message is displayed in the header of the report.

For further information about the calibration concept, refer to the COBI CD.

Working Information window (c 501)

➔ **Calibration** > **Status** > select photometric test > **Calibration Result** > select test for **c** 501 > **Working Information**

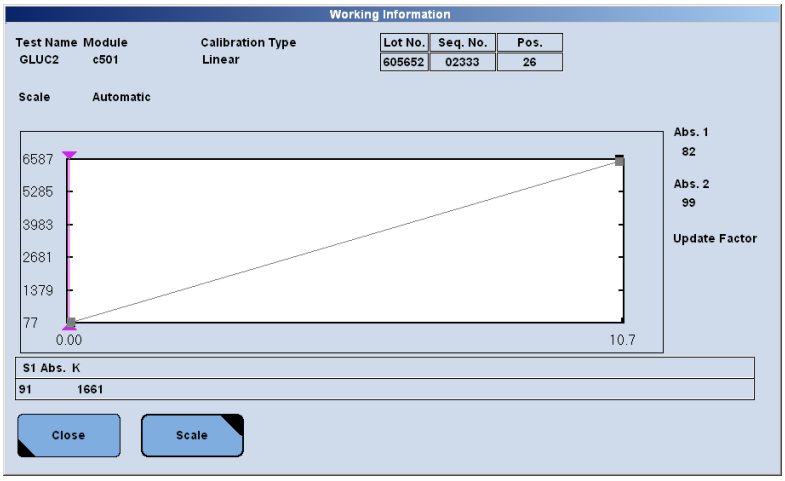


Figure E-175 Working Information window

Use this window to display the calibration curve for any photometric test (**c** 501).

The absorbance is plotted on the Y-axis. The concentration or log of the concentration, based on the calibration type, is plotted on the X-axis.

Test Name This field displays the selected test.

Module This field displays the name of the module on which the selected test was performed, e. g. C1 or C2.

Calibration Type This field displays the calibration curve type for the selected test. The calibration type is programmed on the **Utility** > **Application** > **Calib** window. The options are: **Linear**, **Spline**, **Line Graph, RCM**, **RCM2T1**, and **RCM2T2**.

Lot No. This field displays the lot number of the **cobas c** pack used for the calibration.

Sequence This field displays the sequence number of the **cobas c** pack used for the calibration.

Pos. This field displays the position where the **cobas c** pack is located.

Scale This field displays the scale, **Automatic** or **Manual**, selected on the **Scale Setting** window.

Abs. 1 This field displays the first replicate absorbance result for the selected calibrator.

Abs. 2 This field displays the second replicate absorbance result for the selected calibrator.

Update Factor This field displays the update factor for the selected calibration. The update factor is the factor that is used to recalculate the S1Abs in case of a blank calibration, and S1Abs and K factor in case of a span calibration.

👁 For more information, refer to the COBI CD, section *Calibration update types*.

S1 Abs. This field displays the mean absorbance of both replicates of the calibrator (1).

S2 Abs.-S6 Abs. This field displays the absorbance of calibrators (2)-(6), if necessary.

K This field displays the reciprocal value of the calibration curve (K factor). For tests using other calibration methods, this number is automatically updated following each successful calibration.

A This field displays the nonlinear coefficient A (slope).

B This field displays the nonlinear coefficient B (intercept).

C This field displays the nonlinear coefficient C (cubic spline exponential).

L This field displays the bichromatic absorbance difference of the lipemic serum index.

H This field displays the bichromatic absorbance difference of the hemolysis index.

I This field displays the bichromatic absorbance difference of the icterus index.

Button

Scale Choose this button to display the **Scale Setting** window. This window is used to set the scale of the **Working Information** window.

See *Scale Setting window – Working Information* on page E-286.

Scale Setting window – Working Information

➔ **Calibration** > **Status** > select photometric test > **Calibration Result** > select test > **Working Information** > **Scale**

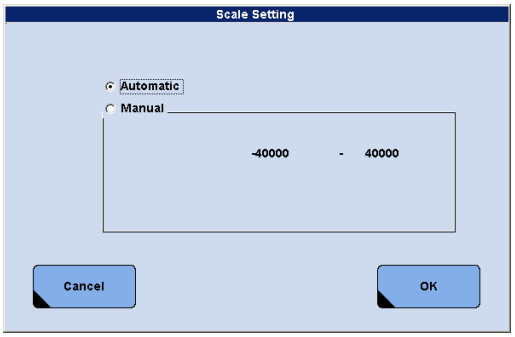


Figure E-176 Scale Setting window

This window is used to define the scaling for the graphics display in the **Working Information** window. You can choose between automatic scaling by the system and manual scaling.

Automatic Select this option to display the graphics display in the **Working Information** window automatically adjusted by the system. In this case, the system determines the appropriate scale setting necessary to display the calibration values.

Manual Select this option to scale the graphics display in the **Working Information** window manually. You can enter absorbance values for the lower and upper limits from -40000 to 40000.

Calibration Factor window (c 501)

➔ **Calibration** > **Status** > select photometric test > **Calibration Result** > select test > **Calibration Factor**

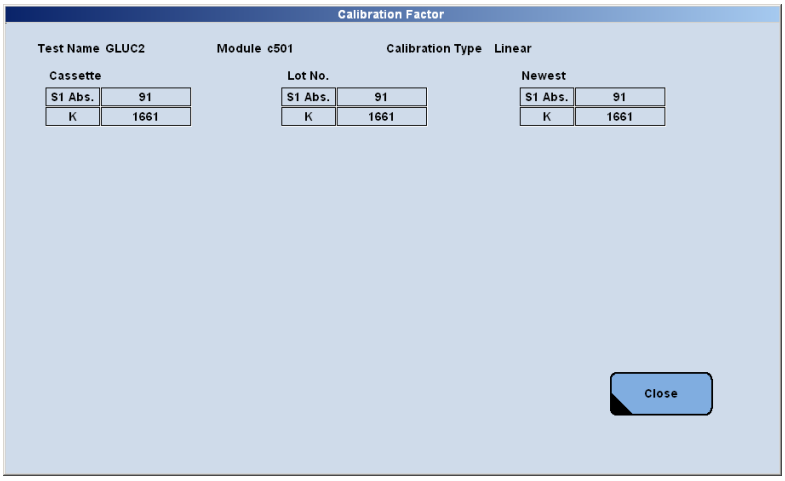


Figure E-177 Calibration Factor window (**c** 501)

Use this window to display the calibration factors of the selected **cobas c** pack on the **Calibration Result** screen.

Test Name This field displays the selected test.

Module This field displays the name of the module for which the results apply.

Calibration Type This field displays the calibration curve type for the selected test. The calibration type is programmed on the **Utility** > **Application** > **Calib** window. The options are: **Linear**, **Spline**, **Line Graph, RCM**, **RCM2T1**, and **RCM2T2**.

Cassette This table displays the calibration values (**S1 Abs**. and **K**) of the cassette calibration.

If 9999 (**S1 Abs.**) and 99999 (**K**) are displayed no calibration data exists for this **cobas c** pack.

👁 See *Lot and cassette calibrations for cobas c packs* on page B-161.

Lot No. This table displays the calibration values (**S1 Abs.** and **K**) of the lot calibration.

If 9999 (**S1 Abs.**) and 99999 (**K**) are displayed no lot calibration exists, and the **Newest** calibration values are used for result calculation, if the **cobas c** pack has no own cassette calibration.

Example: A **cobas c** pack of a new lot that was loaded on the instrument does not have any calibration data. Always the newest calibration data (the data of the last valid lot calibration) are transferred.

👁 See *Lot and cassette calibrations for cobas c packs* on page B-161.

Newest This table displays the calibration values (S1 Abs. and K) of the newest lot calibration, which will be transferred to a new **cobas c** pack of a new or the same lot.

If 9999 (**S1 Abs.**) and 99999 (**K**) are displayed no lot calibration exists for this test which can be transferred to a new **cobas c** pack of a new or the same lot.

See *Lot and cassette calibrations for cobas c packs* on page B-161.

Reaction Monitor window (c 501)

➔ **Calibration** > **Status** > select photometric test > **Reaction Monitor**

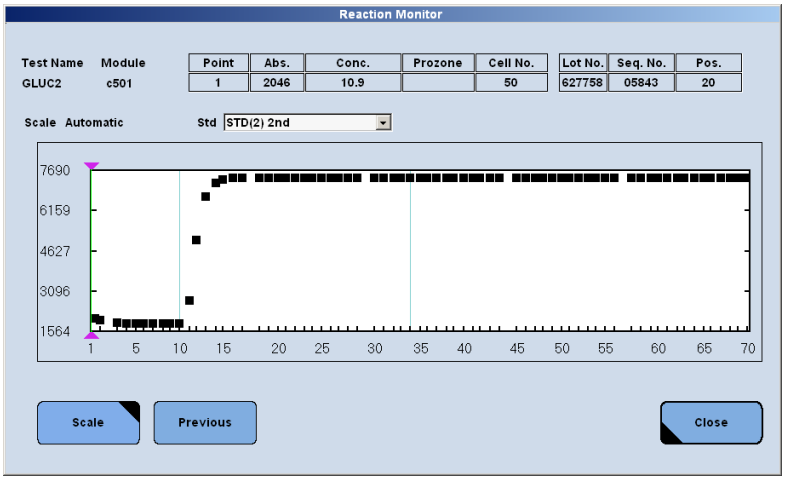


Figure E-178 Reaction Monitor window (**c** 501)

Use this window to view the reaction graph for the calibrator measurement of a specific test of the most recent calibration.

The measuring points are displayed in absorbance (X-axis) over time (Y-axis). The Y-axis displays 70 measuring points with a time interval of about 8 seconds between two points. 15 measuring points are approximately 2 minutes.

Test Name This field displays the selected test in the **Calibration** > **Status** screen.

Module This field displays the name of the module on which the test was performed, e. g. C1 or C2.

Point This field displays the measuring point selected in the graph. 1 to 70 measuring points are displayed depending on the application definitions.

See *Reaction monitoring* on page A-85.

Abs. This field displays the absorbance value for the selected measuring point.

Conc. This field displays the given concentration of the measured calibrator.

Prozone This field displays a prozone value if it is given in the application definition.

Cell No. This field displays the number of the reaction cell in which the reaction was measured.

Lot No. This field displays the lot number of the used **cobas c** pack.

Sequence This field displays the sequence/serial number of the used **cobas c** pack.

Pos. This field displays the reagent position on the instrument.

Std Use this list box to select the calibrator (calibrator level and 1st or 2nd replicate), whose reaction curve is to be displayed in the graph. Select the desired calibrator from the list and press <Enter>.

Scale This field displays the scale, **Automatic** or **Manual**, selected on the **Scale Setting** window.

Graph area

This area displays the graph of the calibrator measurement. Choose a measuring point to display the corresponding absorbance value in the **Abs.** field.

See *Abs.* on page E-289.

Buttons

Scale Choose this button to display the **Scale Setting** window. Use this window to adjust the scaling of the graph.

See *Scale Setting window – Reaction Monitor* on page E-291.

Previous Choose this button to display the reaction graph of the previous calibration (same replicate and calibrator level).

Scale Setting window – Reaction Monitor

➔ **Calibration** > **Status** screen > select photometric test > **Reaction Monitor** > **Scale**

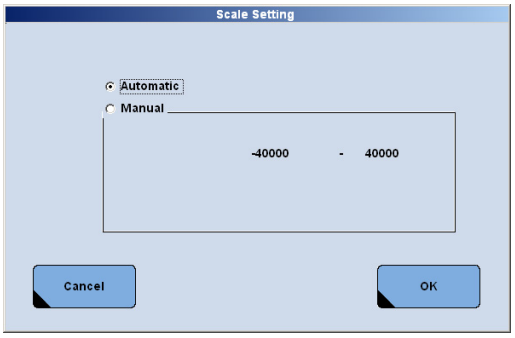


Figure E-179 Scale Setting window

This window is used to define the scaling for the graphics display in the **Reaction Monitor** window. You can choose between automatic scaling by the system and manual scaling.

Automatic Select this option to display the graphics display in the **Reaction Monitor** window automatically adjusted by the system. In this case, the system determines the appropriate scale setting necessary to display the calibration values.

Manual Select this option to scale the graphics display in the **Reaction Monitor** window manually. You can enter absorbance values for the lower and upper limits from -40000 to 40000.

Instrument Factor window

➔ **Calibration** > **Status** > **Instrument Factor**

This window can be viewed on any password level. To edit the data a supervisor level (or higher) is necessary.

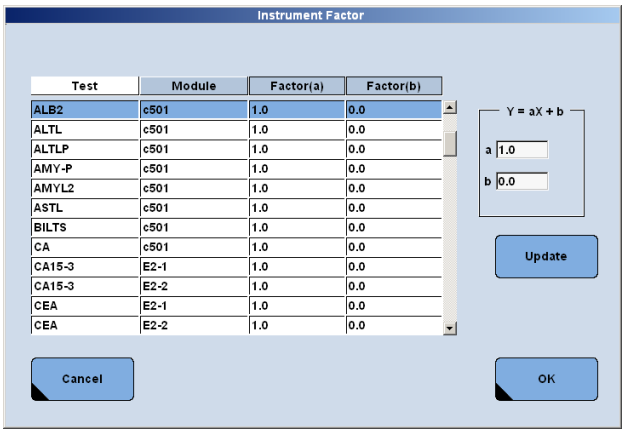


Figure E-180 Instrument Factor window

This window shows the calibration factors for all installed tests on the system.

If the values for **a** and **b** are unequal to 1 the concentration values for controls and samples are adjusted by using the equation Y= aX+b. This might be used to obtain a correlation with other methods, to allow temperature conversion for enzymes (refer to the respective instructions for use), etc.

Factors list

This list shows all installed tests and their corresponding instrument factors. The factors correspond to the slope (factor a) and the intercept (factor b) of the graph defined by the linear equation, Y = aX + b.

Test The **Test** column displays the name of the test.

Module The **Module** column displays the module name and the corresponding measuring cell.

Factor (a) The **Factor (a)** column displays the factor (a) representing the slope (-99999 to 999999). The default value is 1.

Factor (b) The **Factor (b)** column displays the factor (b) representing the intercept (-99999 to 999999). The default value is 0.

Y = aX + b area

This area contains 2 text boxes that display the values for the test/module combination selected in the factors list. To alter the values for a specific test/module combination, select the appropriate entry in the factors list and enter the new values for a and b in the corresponding text boxes.

a This text box is used to enter the value for factor **a** (-99999 to 999999).

b This text box is used to enter the value for factor **b** (-99999 to 999999).

- **c** 501 tests: Enter the intercept in the measuring unit currently used for the test.
- **e** 601 tests: Enter the intercept in the default unit of the test.

Start Up Setting window

➔ **Calibration** > **Status** > **Start Up Setting**

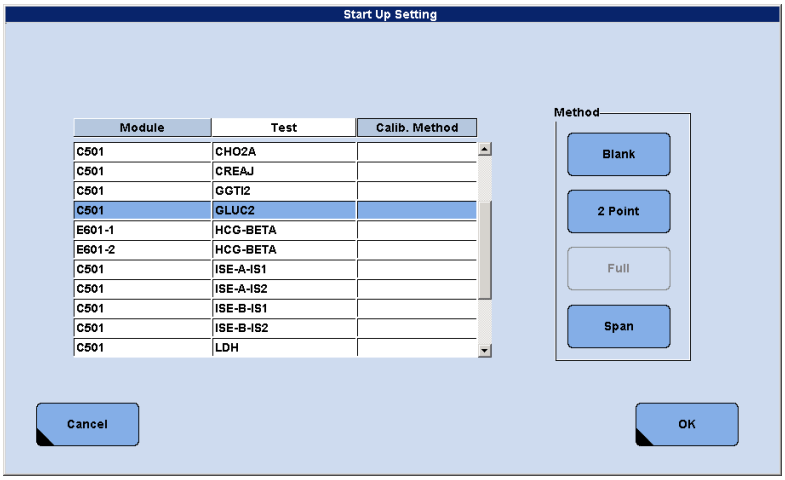


Figure E-181 Start Up Setting window

Use this window to define tests for a start up calibration. A start up calibration is performed at the beginning of a run.

When the **Start Up** button is selected either from **System Overview** > **Calibration and QC Select** or from **Calibration** > **Status**, all calibration selections from the **Start Up Setting** window will be requested. A start up calibration overrides selections appearing on the **Calibration** > **Status** screen.

A start up calibration can also be performed during routine operation by selecting the **Start Up** button on the **Calibration** > **Status** screen and loading the required calibrators.

Start Up list

This list displays all tests available on the system and their start up calibration method if defined. It can be sorted by module or test name by selecting the appropriate tab (column header). A white background shows the selected sorting function.

Module The **Module** column displays the module.

Test The **Test** column displays the test.

Calib. Method The **Calib. Method** column displays the selected calibration method for a start up calibration. The default value is no entry, which means that this test is not activated for start up calibration.

Method area

The **Method** area contains 4 buttons: **Blank**, **2 Point**, **Full**, and **Span**. Depending on the selected test not all options might be available.

Blank Select this button to get a calibration recommendation for a blank calibration.

2 Point Select this button to get a calibration recommendation for a two point calibration.

Full Select this button to get a calibration recommendation for a full calibration.

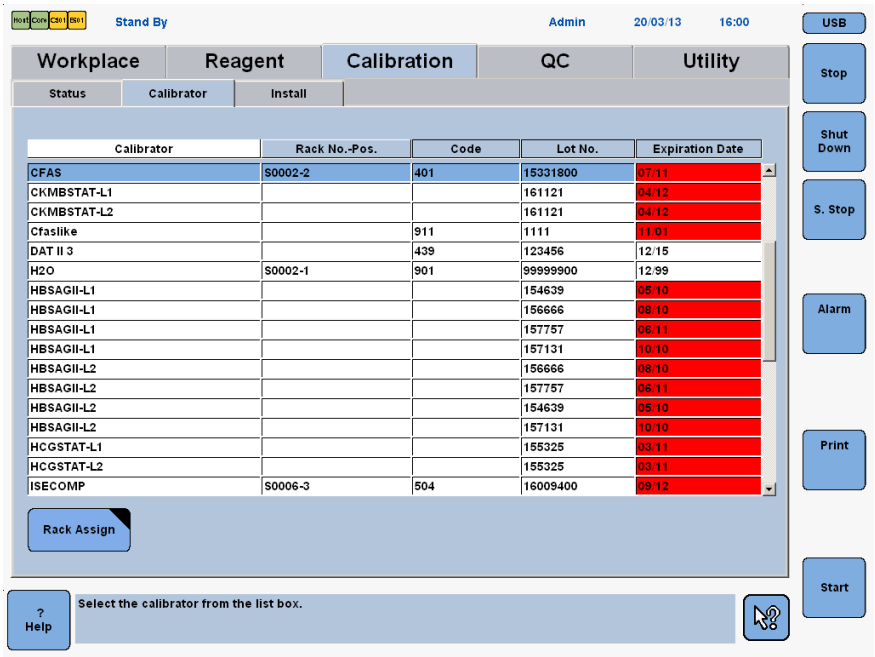
- For **e** 601, only **Full** is available.
- For **c** 501, for all non linear calibrations all methods are available. Refer to the instructions for use for the correct calibration method.

Span Select this button to get a calibration recommendation for a span calibration.

Calibrator screen

➔ **Calibration** > **Calibrator**

This window can be viewed on any password level. To edit the data a supervisor level (or higher) is necessary.



Calibrator	Rack No.-Pos.	Code	Lot No.	Expiration Date
CFAS	S0002-2	401	15331800	07/11
CKMBSTAT-L1			161121	04/12
CKMBSTAT-L2			161121	04/12
Cfaslike		911	1111	11/01
DAT II 3		439	123456	12/15
H2O	S0002-1	901	99999900	12/99
HBSAGII-L1			154639	05/10
HBSAGII-L1			156666	08/10
HBSAGII-L1			157757	06/11
HBSAGII-L1			157131	10/10
HBSAGII-L2			156666	08/10
HBSAGII-L2			157757	06/11
HBSAGII-L2			154639	05/10
HBSAGII-L2			157131	10/10
HCGSTAT-L1			155325	03/11
HCGSTAT-L2			155325	03/11
ISECOMP	S0006-3	504	16009400	09/12

Figure E-182 Calibrator screen

This screen is used to verify the installed calibrator lot and its expiration date, and to view and assign calibrator positions.

See *Assigning calibrator positions* on page B-178.

Calibrator list

This list displays the name of the calibrator and its assigned position if defined, code number (**c** 501), lot number and expiration date. It can be sorted by calibrator name or rack number. A white background distinguishes the selected column tab.

If **?????-L1** or **?????-L2** is displayed as a name of a calibrator (**e** 601 only) the corresponding application is not installed.

Calibrator The **Calibrator** column displays the calibrator name (**c** 501) or the test name and calibrator level (e.g., T4-L2) (**e** 601).

Rack No.-Pos. The **Rack No.**-**Pos.** column displays the rack number and position of the calibrator (e.g., 1234-3 for rack no. 1234, position 3). This function is used if the operator wants to work without barcoded calibrators.

Racks which have a position assignment cannot be used for barcoded calibrator vials. Mixed mode is also not possible.

Code The **Code** column displays the calibrator code number (**c** 501 only).

Lot No. The **Lot No.** column displays the lot number of the installed calibrator. If another calibrator lot should be used it has to be installed in the **Calibrator** > **Install** screen. If a calibrator lot is used which is not installed, the system will not process it.

Expiration Date The **Expiration Date** column displays the expiration date of the installed calibrator lot.

If the **Expiration Date** column is highlighted in red, the corresponding calibrator is expired. It is not possible to perform a calibration with expired calibrators on **e** 601 modules.

Buttons

Rack Assign Choose this button to display the **Rack Assignment** window. Use this window to assign a position to a calibrator, if for example, the calibrator barcode is unreadable.

See *Calibrator Rack Assignment window* on page E-298.

Calibrator Rack Assignment window

➔ **Calibration** > **Calibrator** > **Rack Assign**

This window can be viewed on any password level. To edit the data a supervisor level (or higher) is necessary.

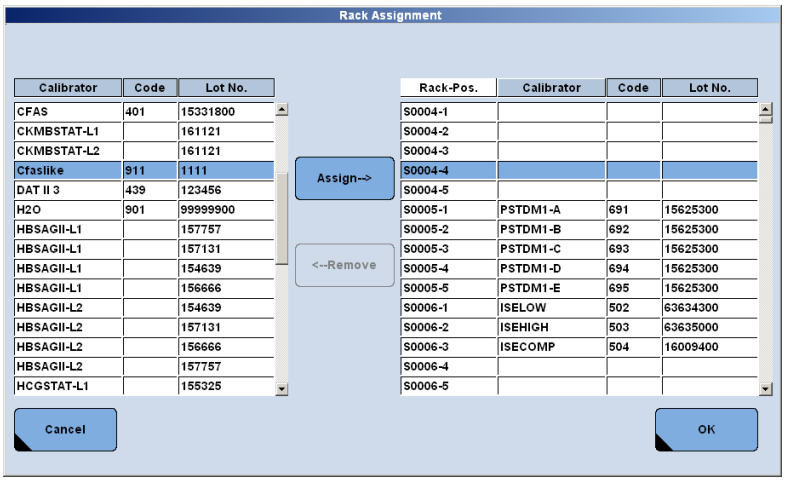


Figure E-183 Rack Assignment window

This window is used to assign a non-barcoded calibrator to a position of a black calibrator rack.

You can either work with barcoded calibrator vials or with non-barcoded calibrator vials. If you work with non-barcoded calibrator vials, you have to assign each calibrator to a unique rack number and position of a calibrator rack.

The instrument identifies non-barcoded calibrators by means of the rack number and position assignment of this window.

For more information, see:
Sample racks on page A-59
Sample identification on page A-62
Assigning calibrator positions on page B-178

Do not use barcoded calibrator vials on racks that have been assigned for non-barcoded calibrator vials.

- In this case the instrument generates an alarm and no calibration is performed. The rack is passed to the output buffer.
- If you have to manually assign a calibrator vial to a calibrator rack, for example, due to an unreadable barcode, place this calibrator vial on the correct position.

Calibrator list

This list, on the left side of the window, displays all calibrators (in Test Name – Calibrator Level Format) installed on the system.

Calibrator The **Calibrator** column displays the name of the calibrator and its level (for example, T4-L2 for test name T4, calibrator level 2).

Code The **Code** column displays the calibrator code number (**c** 501 only).

Lot No. The **Lot No.** column displays the lot number of the installed calibrator.

Position list

This list, on the right side of the window, displays all possible positions.

Rack-Pos. The **Rack-Pos.** column displays the rack number and position.

Different designations for calibrator racks

There are following designations for the calibrator racks:

- Rack color: black
- Label on rack: C001 - C999
- Software displays: S00001 - S00999 or S0001 - S0999

Calibrator The **Calibrator** column displays the name of the calibrator and its level (e.g., T4-L2 for test name T4, calibrator level 2) assigned to the corresponding position.

Code The **Code** column displays the code of the calibrator assigned to this position (**c** 501 only).

Lot No. The **Lot No.** column displays the lot number of the calibrator assigned to this position.

Buttons

Assign--> This button is used to assign the calibrator currently selected in the calibrator list to the position currently selected in the position list.

<--Remove This button is used to remove the calibrator assigned to the position selected in the position list from that position.

If a position is already assigned, it has to be first removed and then it can be newly assigned.

If **???** is displayed in the calibrator name list (**e** 601only) the corresponding application is not installed.

Install screen

➔ **Calibration** > **Install**

This screen can be viewed on any password level. To edit the data a supervisor level (or higher) is necessary.

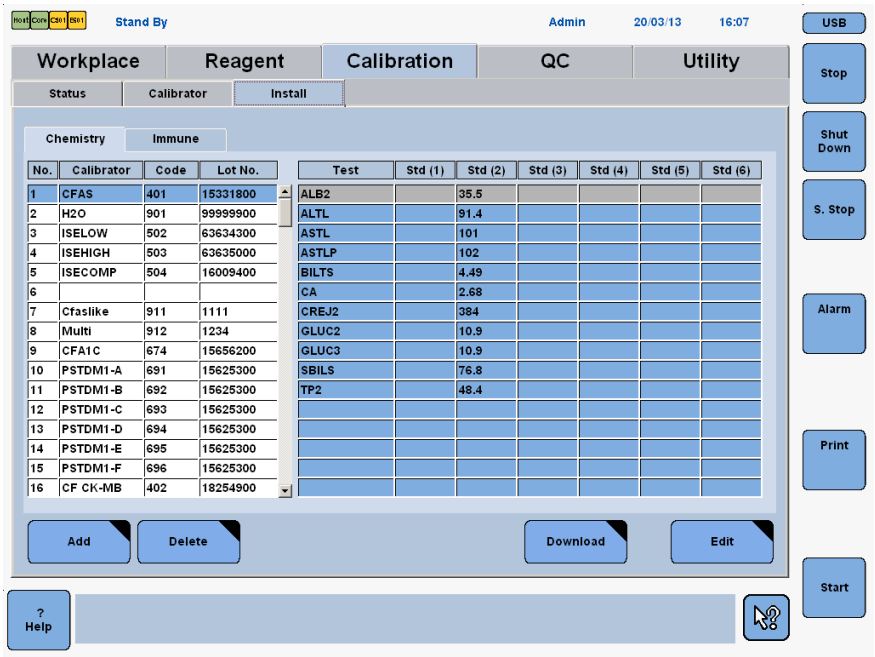


Figure E-184 Calibration > Install > Chemistry screen

The **Calibration** > **Install** screen is divided into two tabs, **Chemistry** and **Immune** (only in a module configuration with **c** 501 and **e** 601 modules). Choose the corresponding tab to access the respective sub-screen.

Use the **Chemistry** tab to add, delete, download or edit calibrators for test performed on the **c** 501module. Only one lot of the same calibrator code can be used at one time.

Use the **Immune** tab to download and delete calibrators for tests performed on the **e** 601. Up to 5 different lot numbers for the same *inpack calibrator* can be listed (calibrator that is delivered together with the corresponding **cobas e** pack). For all other calibrators only one lot number of the same calibrator code can be used at the same time.

Calibrator list

The list box on the left displays information for all calibrators entered in the system.

No. The **No.** column displays the consecutive number for the calibrators.

Calibrator The **Calibrator** column displays the name of each calibrator.

If **?????-L1** or **?????-L2** is displayed as a name of a calibrator (**e** 601 only) the corresponding application is not installed.

Code The **Code** column displays the calibrator code number (**c** 501 only).

Lot No. The **Lot No.** column displays the lot number of the installed calibrator.

Test list

The list box on the right displays details about the tests assigned to the calibrator highlighted in the left list box (**c** 501 only).

Test The **Test** column displays the test name.

Std (1)... Std (6) For **c** 501 the target value for each calibrator is displayed in the appropriate column.

For **e** 601 tests no target values are displayed. The target values are displayed on the **Calibration Result (immune)** window after the calibration is completed.

Buttons

Add (***c** 501* only) Select an empty position and choose this button to display the **Assignment** window. Use the **Assignment** window to manually add a Non-Roche Diagnostics calibrator to the system (supervisor level).

See *Assignment window* on page E-302.

Delete Use this button to delete a calibrator from the system. Select the calibrator to be deleted from the left list box, then choose **Delete**. A confirmation window appears. Choose **Yes** to delete the selected calibrator. Choose **No** to close the window without deleting (supervisor level).

Download Use this window to download calibrator information from the **cobas** link, if a new lot is needed, or if a new version (updated target values, **c** 501 only) of the used lot is available (supervisor level).

See *Download window* on page E-303.

Edit (***c** 501* only) Select the calibrator which has to be edited and choose this button to display the **Edit Calibrator** window. Use the **Edit Calibrator** window to assign calibrator target values for calibrators (supervisor level).

See *Edit Calibrator window (c 501 only)* on page E-307.

Assignment window

➔ **Calibration** > **Install** > **Chemistry** > **Add** (**c** 501 only)

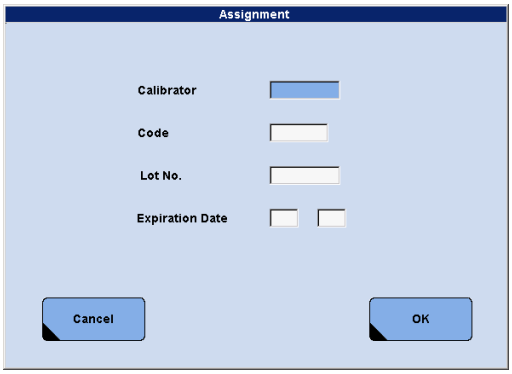


Figure E-185 Assignment window

Use the **Assignment** window to add a Non-Roche Diagnostics calibrator to the system or to change calibrator specifications (name, code, …) from an existing calibrator.

If you try to add a calibrator that is already defined on the system (the same **Code**), you receive a warning message.

Calibrator Use this text box to define a name for the calibrator. Type in the name (up to 8 characters) and press <Enter>.

Code Use this text box to enter the code number associated with the calibrator.

Ensure that the calibrator code is not used. For Non-Roche Diagnostics calibrators or ISE calibrators use the code numbers 901 to 998.

Lot No. Use this text box to define a lot number for the calibrator. Type in the lot number (up to 8 characters) and press <Enter>.

Expiration Date Use these two text boxes to specify the expiration date for the calibrator. Type the year of the expiration (0 to 99) in the first text box and press <Enter>. Type the month of the expiration (1 to 12) in the second text box and press <Enter>.

Download window

➔ **Calibration** > **Install** > **Download**

This window can be accessed by an operator with supervisor (or higher) level only.

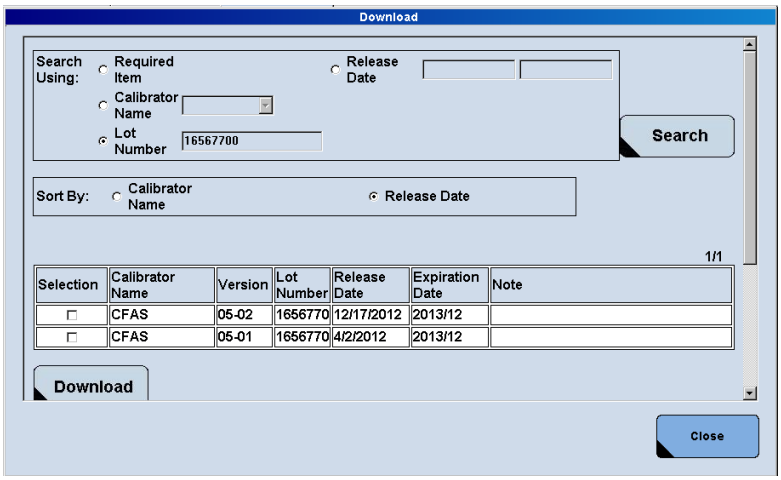


Figure E-186 Confirmation window (new calibrator code)

Use this window to search for calibrator data on **cobas** link. After a successful search a table appears in the lower half of the window. This table displays all calibrators that match the search criteria.

No update of manually edited calibrator values (c 501)

In case a calibrator concentration has been manually edited, this calibrator concentration will not be updated when you download new calibrator data for an installed lot from **cobas** link. There is no indication in the software if the calibrator concentration was manually edited before.

- Check the calibrator concentrations after downloading.
- If you want to return to the original calibrator concentration, delete the calibrator and download it again from **cobas** link. Perform calibration before you resume routine operation.

In case a calibrator code already exists use this window to confirm overwriting the calibration information already stored on the system for this calibrator code.

Calibrator settings, for example position assignment, are not overwritten.

Search Using area

Required item This option is used to search for an item that was not found in the system software while barcode reading has been performed.

Release Date This option is used to search for calibrators that have been released in the time frame entered here.

Calibrator Name This option is used to display all calibrators with the same name which are available on the **cobas** link in the list below.

Lot Number This option is used to display a specific lot number of calibrator in the list below.

Enter the first six digits of the lot number followed by two zeros (XXXXXX00).

Search Use this button to search for the selected calibrator parameters on **cobas** link.

Sort By area

Use this function to sort the calibrator list by calibrator name or release date.

Calibrator Name Use this function to sort the calibrator list by calibrator name.

Release Date Use this function to sort the calibrator list by release date.

Download area

Use this area to select the desired item for download.



Recommendation for download

If there are more calibrator entries for the same lot number, always download the calibrator data with the latest release date.

[Next>] Choose **[Next >]** to display more search results.

Page/pages Depending on the number of items in the table there can be more than one page. For example, the information **2/3** means that page 2 of 3 is displayed.

Selection This column displays the check box of the calibrators. Select the desired item for download.

Calibrator Name This column displays the name of the calibrator.

Version This column displays the version number of the downloaded calibrator. If the calibrator information, e. g. target value for a test, is changed, a new version number is available on **cobas** link (**c** 501 only).

Lot Number This column displays the lot number of the calibrator.

Release Date This column displays when the information was released by Roche Diagnostics.

Expiration Date This column displays the expiration date of the calibrator.

Note This column displays additional information about the calibrator.

Download Use this button to download the calibrator parameters from **cobas** link to the system software.

Confirmation window (calibrator download)

➔ **Calibration** > **Install** > **Download** > **Download**

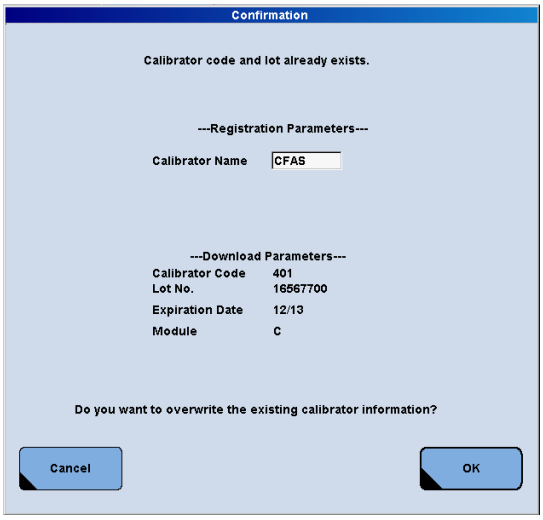


Figure E-187 Confirmation window

The **Confirmation** window displays the downloaded calibrator data. For **c** 501 calibrator you can edit the calibrator name.

Message area

The message area informs you about the current download action. Usually calibrator parameters are added.

For **c** 501, it is possible to add parameters for calibrators which already exist. In this situation, the message area informs you that the calibrator code or the calibrator code and lot already exist.

Registration Parameters area

This area displays the registration parameters.

Calibrator Name This field displays the calibrator name as defined by Roche Diagnostics.

For **c** 501 calibrators the name can be changed.

Download Parameters area

This area displays the download parameters.

Calibrator Code This field displays the calibrator code. The calibrator code is displayed for **c** 501 calibrators only.

Lot No. This field displays the lot number of the calibrator.

Expiration Date This field displays the expiration date of the calibrator.

Module This field displays the module for which the calibrator parameters are to be downloaded.

Edit Calibrator window (c 501 only)

➔ **Calibration** > **Install** > **Chemistry** > **Edit**

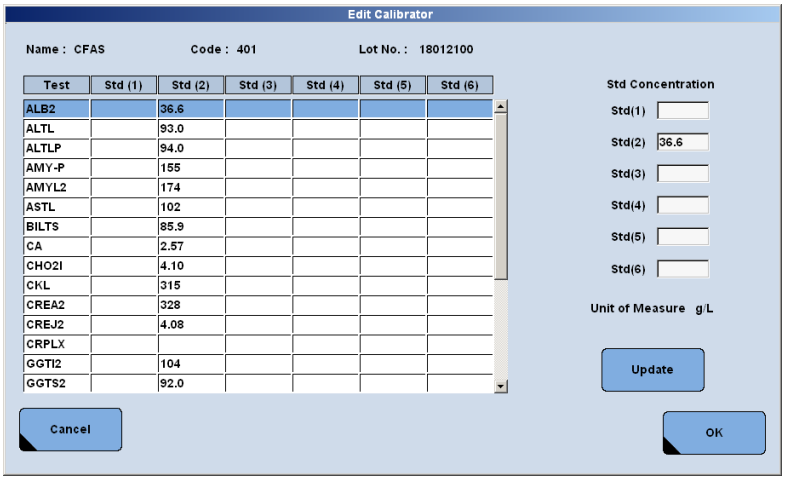


Figure E-188 Edit Calibrator window

Use the **Edit Calibrator** window to assign calibrator target values for calibrators. Highlight each test and enter the corresponding concentration. You can edit an existing value. If you have added a new calibrator (Non-Roche Diagnostics calibrator) you have to enter the target values for the new calibrator in this window.

For more information, see:
Editing calibrator concentrations (c 501) on page B-189
Changing decimal places used for reportable data (c 501) on page B-191

No update of manually edited calibrator values (c 501)

In case a calibrator concentration has been manually edited, this calibrator concentration will not be updated when you download new calibrator data for an installed lot from **cobas** link. There is no indication in the software if the calibrator concentration was manually edited before.

- Check the calibrator concentrations after downloading.
- If you want to return to the original calibrator concentration, delete the calibrator and download it again from **cobas** link. Perform calibration before you resume routine operation.

Name This field displays the name of the calibrator.

Code This field displays the calibrator code.

Lot No. This field displays the lot number of the calibrator.

Test list

The list box on the left displays the tests assigned to the calibrator.

Test The **Test** column displays the test name.

Std (1)... Std (6) The target value for each calibrator is displayed in the appropriate column.

Std Concentration area

This area contains 6 text boxes labeled **Std (1)** through **Std (6)**. Use these text boxes to type the calibrator concentration (target values) (0 to 999999) used during calibration of the selected assay. Up to 6 calibrators can be defined.

For the **c** 501 (ISE) the Std concentrations must be entered here.



The number of decimal places used for Std (1) defines the number of decimal places used for reportable data. This is only valid for **c** 501 tests.

It is recommended to select the number of decimal places at the time of installing the application.

Unit of measure This field displays the unit of measure as defined in the application.

Update Choose this button to update the list box with the new value.

QC menu

This chapter provides a detailed description of the **Quality Control** menu and the corresponding screens. In the **Quality Control** menu you can view which controls need to be measured and request them for measurement. You can also view quality control results, accumulate them to the cumulative quality control and apply statistical rules, realtime QC. Controls can be installed, edited or deleted via this menu. Information about quality controls and to which test they are linked is also available here.

In this chapter *Chapter* 26

Status screen E-311
Status list E-311
Buttons E-312
Routine QC window E-313
Routine QC list E-313
Stand By Bottle QC window E-314
Stand By Bottle QC list E-314
Button E-315
Automatic QC Unloading window E-316
Buttons E-316
Run Status screen E-317
QC run status details E-318
QC run status chart E-319
Individual screen E-320
Individual list E-320
Buttons E-321
Individual QC Chart window E-322
Chart list E-323
Levey-Jennings chart E-323
Buttons E-324
Comment window E-325
Select Chart window E-326
Buttons E-326
Realtime QC window E-327
Rule area E-328
Yoden Twin Plot E-328

Buttons E-329
Accumulate Data window E-330
Select Control window E-331
Select Rules window E-332
Reject Data window E-333
Cumulative screen E-334
Cumulative list E-334
Buttons E-335
Cumulative QC Chart window E-336
Chart list E-337
Levey-Jennings chart E-338
Button E-338
Select Chart window E-339
Buttons E-339
Control screen E-340
Button E-341
QC Rack Assignment window E-342
Control list E-342
Rack list E-343
Buttons E-343
Install screen E-344
Control list E-345
Test list E-345
Buttons E-346
Add Control window E-347
Download window E-348
Search Using area E-349
Sort By area E-349
Download area E-350
Edit Control window E-351
Test list E-352
Individual and Cumulative areas E-352
Confidence Limit area E-353
Buttons E-353

Status screen

➔ **QC** > **Status**

Use the **Status** screen to view information on QC statuses for all or a selected module. From this screen you can also select standby reagents which should to be controlled.

For more information on special operations, see:
Requesting QC measurements on page B-205
To perform controls for active reagents on page B-205
To perform controls for standby reagents on page B-206
Automatic QC measurement on page B-228

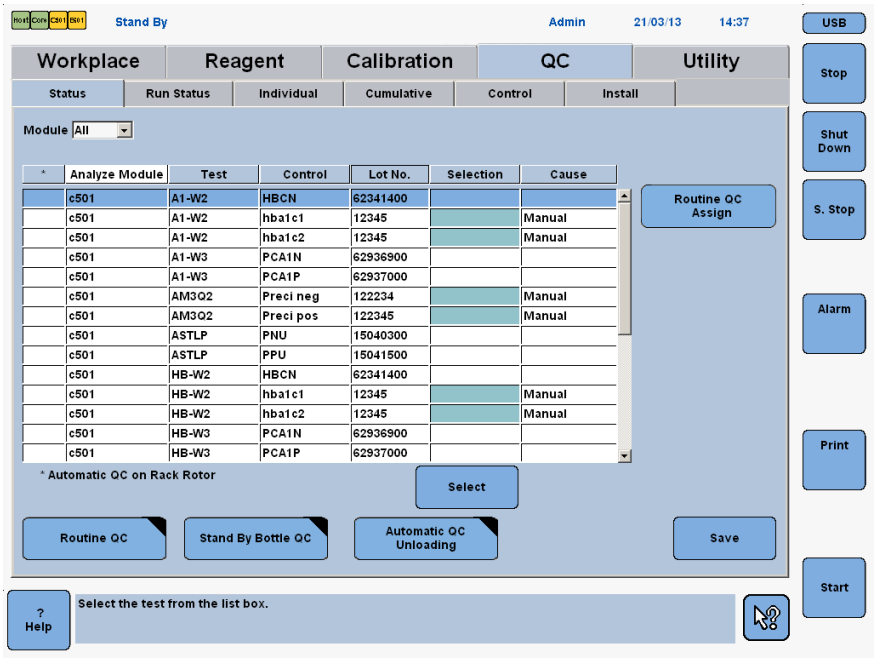


Figure E-189 Status screen

Module Use this list box to select the module to view information. Information is displayed in the **Status** list.

Status list

This list displays information about controls currently active on the system and can be sorted by module, test name, control name, selection, or cause. A white background distinguishes the selected column tab.

* The asterisk in this column indicates the control for the test is programmed as automatic QC.

See *Automatic QC measurement* on page B-228.

Analyze Module This column displays the module name and measuring channel for which the control can be selected. The modules can be selected in the **Module** list box above.

Test This column displays the short test name of a test that has been activated in the **Install** screen for QC.

Control This column displays the name of the control.

Lot No. This column displays the lot number of the control.

Selection This column displays a green bar when the corresponding test has been selected for QC.

A gray bar is displayed when the system has suggested this test for QC timeout.

To toggle a test's selection, highlight the row corresponding to the test, then use the **Select/Deselect** button. On confirming this selection, by choosing **Save** or via the **Calibration and QC Select** window, a green bar is displayed.

Cause This column displays the cause for the QC selection.

The following causes are available in descending priority:

Timeout	Control interval time expired
Manual	QC has been manually selected (**Select/Deselect** button)

Buttons

Routine QC Assign Use this button to request QC measurements for all controls and tests which are activated in the **QC** > **Install** screen.

Select/Deselect Use this button to toggle a test selection in the status list, i.e., select a non-selected test or deselect a selected test. Selected tests display a green bar in the **Selection** column of the status list.

This button changes from **Select** to **Deselect** and vice versa depending on the status of the control.

Routine QC Use this button to display the **Routine QC** window. This window is used to display the controls that are active and will be used for routine QC test requests. Controls can be activated on the **QC** > **Install** screen.

See *Routine QC window* on page E-313.

Stand By Bottle QC Use this button to display the **Stand By Bottle QC** window. This window is used to select reagent packs for standby QC measurement.

See *Stand By Bottle QC window* on page E-314.

Automatic QC Unloading Use this button to unload auto QC racks from the rack rotor. In the **Automatic QC Unloading** window you can select the rack(s) to be unloaded.

For a description of the **Automatic QC Unloading** window, see *Automatic QC Unloading window* on page E-316.

Save Use this button to save any changes made to this screen.

The button changes from blue to yellow if changes were made. To save the changes choose **Save**. The button changes from yellow to blue.

Routine QC window

➔ **QC** > **Status** > **Routine QC**

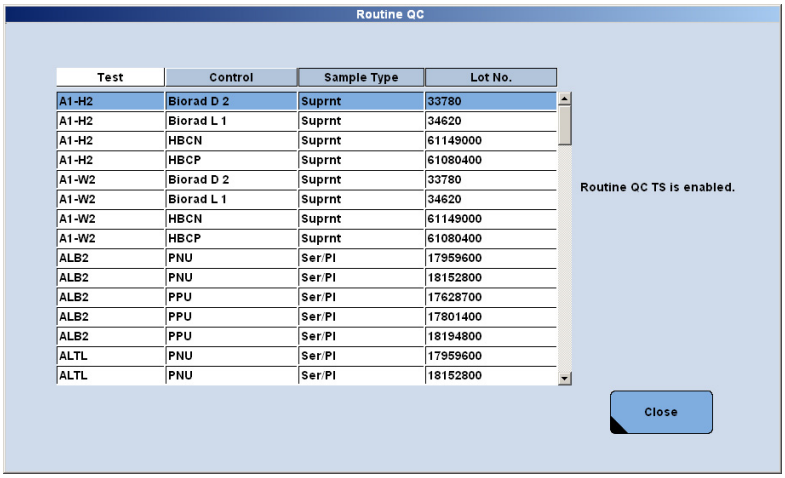


Figure E-190 Routine QC window

Use this window to display all tests and controls that are selected as the routine quality control test request. The tests and controls which are activated in **QC** > **Install** screen are displayed here.

See *Activating control tests* on page B-227.

If no tests are selected for QC, the routine QC tests are performed the next time a QC rack is run if the **Routine QC Test Selection** check box is selected on **Utility** > **System** (**Page 1/4**) > **QC Setting**. This applies only for current **cobas c** pack and **cobas e** pack, not for standby **cobas c** pack and **cobas e** pack.

If the **Routine QC Test Selection** check box is selected on **Utility** > **System** (**Page 1/4**) > **QC Setting**, all tests in this **Routine QC** list will be performed once this QC rack is run. This means that no QC test selection has to be done.

This applies only for current, not for standby reagents.

Routine QC list

This list displays all tests and controls with their sample type and lot number currently activated on the system. It can be sorted by test or control name. A white background distinguishes the selected column tab.

Test The **Test** column displays the short test name.

Control The **Control** column displays the control name.

Sample Type The **Sample Type** column displays the sample type of the control (**Ser/Pl**, **Urine**, **CSF**, **Suprnt** or **Other**).

Lot No. The **Lot No.** column displays the lot number of the control.

Stand By Bottle QC window

➔ **QC > Status > Stand By Bottle QC**

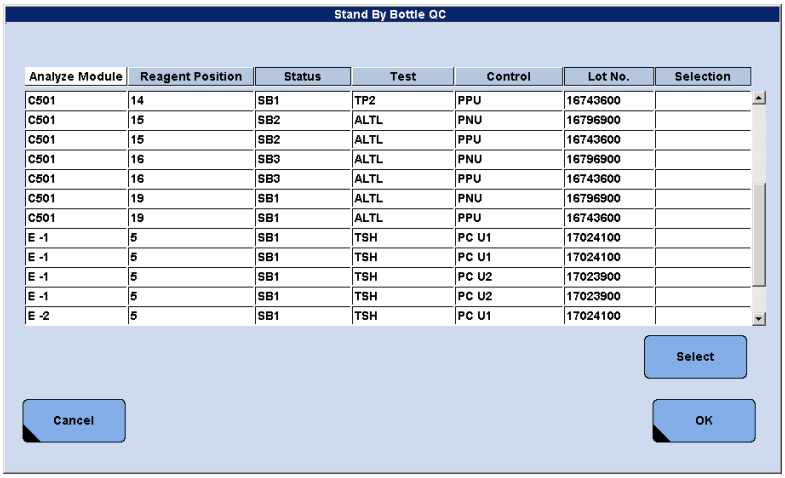


Figure E-191 Stand By Bottle QC window

Use this window to select standby reagents currently on a module for standby QC measurement. All standby reagents are displayed.

For **e** 601 you can only select a standby QC if a calibration is available. If no calibration is available this SB **cobas e** pack is not displayed in this list.

Stand By Bottle QC list

This list displays information for all standby reagent packs currently loaded on the modules. It can be sorted by module, reagent disk position, test name or control name. A white background distinguishes the selected column tab.

Analyze Module This column displays the module name on which the corresponding standby reagent pack is loaded. For the **e** 601 the two measuring cells on one module are also distinguished.

Reagent Position This column displays the reagent disk position on which the corresponding standby reagent pack is loaded.

Status This column displays each reagent's status of precedence. Reagents are indicated by **SB1**, **SB2**, … **SBn**.

For **c** 501 modules, the numbers 1, 2, … n refer to the order of registration on the system. The reagent which is used after the current is **SB1,** the reagent which is used after **SB1** is **SB2** and so on.

For **e** 601 modules **SB1**, **SB2**, … **SBn** refers to the order in which the **cobas e** packs are going to be used.

For more information, see *Priority of cobas e packs* on page B-117.

Test This column displays the short name of the test corresponding to the standby reagent.

Control This column displays the name of the control corresponding to the standby reagent pack.

Lot No. This column displays the lot number of the corresponding standby reagent pack.

Selection This column displays if the corresponding standby reagent pack is selected for QC measurement. If selected, a green bar appears in this column.

Button

Select/Deselect Use this button to toggle a reagent pack selection in the **Stand By Bottle QC** list, i.e., to select a non-selected test or deselect a selected test. Selected tests display a green bar in the **Selection** column of the status list.

Automatic QC Unloading window

➔ **QC** > **Status** > **Automatic QC Unloading**

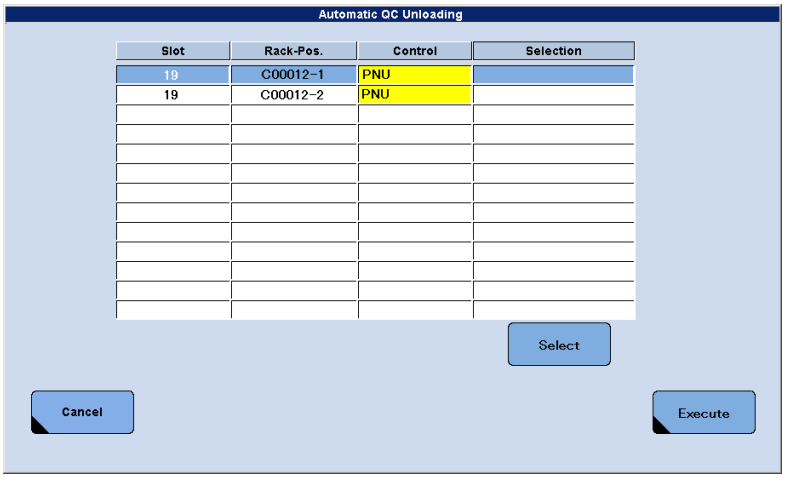


Figure E-192 Automatic QC Unloading window

Use this window to view which QC racks are on the rotor defined as automatic QC racks and to unload the selected automatic QC racks of the rotor.

For more information, see:
Automatic QC measurement on page B-228
Unloading auto QC racks from the rack rotor on page B-229

Slot This field displays the position of the rack in the rack rotor.

Rack-Pos. This column displays the rack position on which the corresponding control is loaded.

Control This column displays the name of the control which is on the QC rack in the rotor.

Selection This column displays if the corresponding control is selected for unloading. If selected, a green bar appears in this column.

Buttons

Select/Deselect Use this button to toggle a control selection in the unloading list, i.e., to select a non-selected control or deselect a selected control. Selected controls display a green bar in the **Selection** column of the unloading list.

Execute The selected QC rack in the corresponding slot on the rack rotor will unloaded.

Run Status screen

➔ **QC > Run Status**

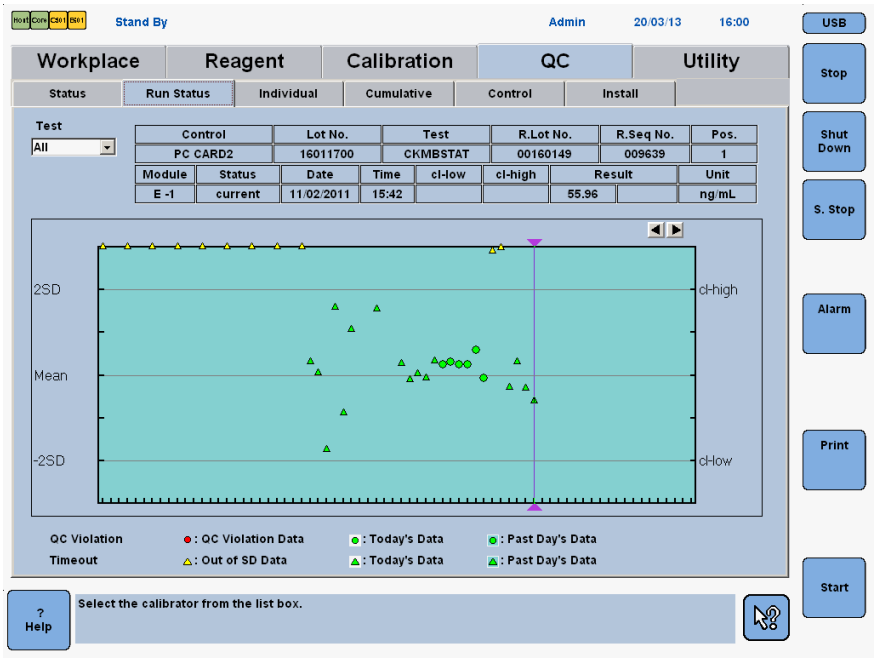


Figure E-193 Run Status screen

Use the **Run Status** screen to get an overview of the latest 500 quality control (**QC**) measurements performed on the analyzer or to view the most recent QC results for one particular test.

Use the **Test** box to select all tests or one specific test to be displayed on the chart. Use the arrows at the top right of the chart to move the focus from one result to the next.

Test box Select a test from this list to view information on QC measurements for one particular test.

For further information, see:
QC run status details on page E-318
QC run status chart on page E-319

QC run status details

The **Run Status** screen consists of a details area in the upper part of the screen, of a run status chart in the center of the screen, and a legend, which explains the symbols used in the chart. The details area in the upper part of the **Run Status** screen displays the following information, which relates to the QC measurement selected on the run status chart:

Control This field displays the name of the quality control material.

Lot No. This field displays the lot number of the quality control material.

Test This field displays the name of the test for which the QC has been performed.

R. Lot No. This field displays the lot number of the reagent (**cobas e** pack for **e** 601, **cobas c** pack for **c** 501 (P)).

R. Seq. No. This field displays the sequence number of the reagent (**cobas e** pack for **e** 601, **cobas c** pack for **c** 501 (P)).

Pos. This field displays the reagent's position in the reagent compartment on the corresponding module.

Module This field displays the module (and channel if applicable) on which the QC has been measured.

Status This field displays a reagent's status of precedence.

For more information, see *Status* on page E-314.

Date This field displays the date when control was measured.

Time This field displays the time when control was pipetted for the selected test.

cl-low This field displays the entered lower confidence limit for the selected test. If the selected test is not configured for QC violation but for timeout calibration, the fields under **cl**-**low** and **cl**-**high** are blank.

cl-high This field displays the entered upper confidence limit for the selected test. If the selected test is not configured for QC violation but for timeout calibration, the fields under **cl**-**low** and **cl**-**high** are blank.

Result This field displays the result of the QC measurement.

Unit This field displays the unit used for the test.

QC run status chart

The chart of the **Run Status** screen displays the latest QC results (up to 500). A legend of the symbols used on the **QC run status** chart is shown below the chart.

Y-axis The left axis shows the standard deviation (**SD**) range from **-2SD** to **+2SD**. The timeout QC points (triangles) refer to the left axis.

The right axis shows the confidence limits (cl) range from **cl-low** to **cl-high**. The QC violation points (circles) refer to the right axis.

Background A white background refers to today's measurements. A green background refers to past days' measurements.

Shape Circles are used when QC violation is activated; triangles are used for timeout setting. The default setting is timeout.

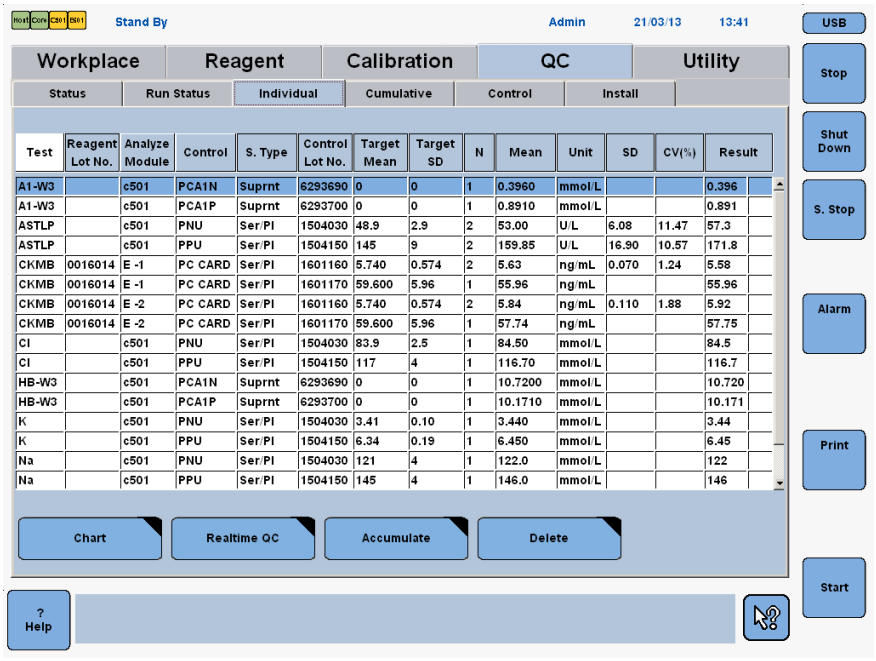
Color Red and yellow denote a QC result falls out of confidence limits or **2 SD** limits, respectively. Green symbols are used for results within the relevant limits.

	Displayed if QC violation is activated	QC result exceeds confidence limit. A calibration is automatically recommended for the affected test.
	Displayed if QC violation is activated	QC result within confidence limits
	Displayed if timeout is activated	QC result falls outside ± **2 SD**
	Displayed if timeout is activated.	QC result within ± **2 SD**

For more information on QC violation, see:
Edit Control window on page E-351
QC-triggered calibration (QC Violation) on page B-157
To activate QC violation on page B-265
QC after calibration on page B-206
QC Violation on page E-499

Individual screen

➔ **QC > Individual**



Test	Reagent Lot No.	Analyze Module	Control	S. Type	Control Lot No.	Target Mean	Target SD	N	Mean	Unit	SD	CV(%)	Result
A1-W3		c501	PCA1N	Suprnt	6293690	0	0	1	0.3960	mmol/L			0.396
A1-W3		c501	PCA1P	Suprnt	6293700	0	0	1	0.8910	mmol/L			0.891
ASTLP		c501	PNU	Ser/Pl	1504030	48.9	2.9	2	53.00	U/L	6.08	11.47	57.3
ASTLP		c501	PPU	Ser/Pl	1504150	145	9	2	159.85	U/L	16.90	10.57	171.8
CKMB	0016014	E -1	PC CARD	Ser/Pl	1601160	5.740	0.574	2	5.63	ng/mL	0.070	1.24	5.58
CKMB	0016014	E -1	PC CARD	Ser/Pl	1601170	59.600	5.96	1	55.96	ng/mL			55.96
CKMB	0016014	E -2	PC CARD	Ser/Pl	1601160	5.740	0.574	2	5.84	ng/mL	0.110	1.88	5.92
CKMB	0016014	E -2	PC CARD	Ser/Pl	1601170	59.600	5.96	1	57.74	ng/mL			57.75
Cl		c501	PNU	Ser/Pl	1504030	83.9	2.5	1	84.50	mmol/L			84.5
Cl		c501	PPU	Ser/Pl	1504150	117	4	1	116.70	mmol/L			116.7
HB-W3		c501	PCA1N	Suprnt	6293690	0	0	1	10.7200	mmol/L			10.720
HB-W3		c501	PCA1P	Suprnt	6293700	0	0	1	10.1710	mmol/L			10.171
K		c501	PNU	Ser/Pl	1504030	3.41	0.10	1	3.440	mmol/L			3.44
K		c501	PPU	Ser/Pl	1504150	6.34	0.19	1	6.450	mmol/L			6.45
Na		c501	PNU	Ser/Pl	1504030	121	4	1	122.0	mmol/L			122
Na		c501	PPU	Ser/Pl	1504150	145	4	1	146.0	mmol/L			146

Figure E-194 Individual screen

On this screen you can see a statistical evaluation and overview of control results for all modules, tests and control measured on the system. Use this screen to display QC charts, to select rules for QC evaluation, to accumulate QC results, and to delete QC results.

For more Information, see:
Configuring and using realtime QC on page B-212
Accumulation of QC results on page B-215
Excluding an individual QC point or adding a comment on page B-211.

Individual list

This list displays information for all non-accumulated QC results. It can be sorted by the test name, module and control name. A white background distinguishes the selected column tab.

- The width of the individual columns can be varied by clicking on the column dividers in the list box header and dragging them to the left or right.
- Most information of the control, displayed in the different columns, are defined on the **QC** > **Install** screen (for example control name, sample type, control lot number).

See *Install screen* on page E-344.

Test This column displays the short name of the test.

*Reagent Lot No. (**e** 601)* This column displays the lot number of the reagent pack used for the QC measurement on **e** 601. The reagent pack lot number is only given for Roche controls.

Analyze Module This column displays the module name on which the QC result was measured. For the **e** 601 the two measuring cells are distinguished.

Control This column displays the name of the used control.

S. Type This column displays the sample type defined for the control (**Ser/Pl**, **Urine**, **CSF**, **Suprnt** or **Other**).

Control Lot No. This column displays the control lot number.

Target Mean This column displays the control target mean for the test.

Target SD This column displays the control target standard deviation for the test.

N This column displays the number of QC measurement of this control.

Mean This column displays the calculated mean of measured results for the corresponding test.

Unit This column displays the unit of the test as defined on **Utility** > **Application** > **Range**.

SD This column displays the standard deviation calculated from N measurements for the corresponding test.

CV(%) This column displays the coefficient of variation calculated from the mean value and the standard deviation for the corresponding test.

Result This column displays the latest or most recent QC result of this control for the selected test.

Buttons

Chart Use this button to display the **Individual QC Chart** window, where the Levey-Jennings chart is displayed.

See *Individual QC Chart window* on page E-322.

Realtime QC Use this button to display the **Realtime QC** window. Use this window to view a Yoden twin plot of the daily routine QC values and to select a QC rule for a selected test.

See *Realtime QC window* on page E-327.

Accumulate Use this button to display the **Accumulate Data** window. Use this window to accumulate data.

See *Accumulate Data window* on page E-330.

Delete Use this button to delete individual QC data for a selected test (supervisor level).

Individual QC Chart window

➔ **QC** > **Individual** > **Chart**

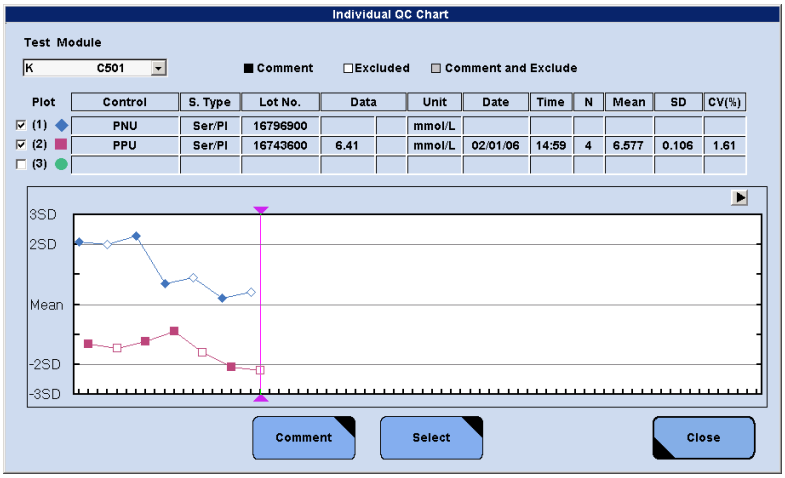


Figure E-195 Individual QC Chart window

Use this window to view the Levey-Jennings chart, to add comments to QC results, and to exclude QC results.

See *Levey-Jennings chart* on page E-323.

The **Individual QC Chart** window displays all recent values per test for each control. The values are displayed in FIFO principle (First In First Out). Up to 150 control values can be plotted per quality control sample.

If no controls are displayed in the chart, you have to select controls on the **Select Chart** window.

See *Select Chart window* on page E-326.

Test Module list box

Use this list box to select the test, module and measuring channel for which the results are to be displayed.

Comment, Excluded, Comment and Excluded

This is a legend describing the points plotted on the chart.

- A comment is attached to this point
- The point is excluded
 Also results from a standby **cobas c** pack/**cobas e** pack are shown as excluded.
- The point is excluded and a comment is attached

For more information, see:
Chart list on page E-323
Buttons on page E-324

Chart list

This list displays detailed information for the point currently selected in the Levey-Jennings chart.

Plot This column displays 3 check boxes for different controls: **(1)**, **(2)**, and **(3)**. Any combination of them can be selected to display the corresponding data on the chart.

- Control (1)
- Control (2)
- Control (3)

Control The **Control** column displays the control name and graphic symbol associated with the different controls. The controls are represented by the following graphic symbols:

The 3 controls can be selected on **QC** > **Individual** > **Chart** > **Select**.

S. Type The **S. Type** column displays the sample type of the control.

Lot No. The **Lot No.** column displays the lot number of the control.

Data The **Data** column displays the measured value of the currently selected point in the chart.

Unit The **Unit** column displays the unit of measure of the currently selected point in the chart.

Date The **Date** column displays the date when the selected control was pipetted by the system.

Time The **Time** column displays the time when the selected control was pipetted.

N The **N** column displays the number of control results that are included in the statistical calculation. Excluded results are not taken into account.

Mean The **Mean** column displays the calculated mean of control results for the currently selected test included in the statistical calculation.

SD The **SD** column displays the calculated standard deviation.

CV(%) The **CV(%)** column displays the coefficient of variation. It is calculated from the mean value and the standard deviation for each test of all results which are included in the statistical calculation.

Levey-Jennings chart

A Levey-Jennings chart provides a visual method of monitoring trends in quality control results. The values of the measured control results are plotted on the Y-axis and date and time on the X-axis. All points should lie within the **±2SD** range. If a point is outside of this range, corrective action is required e.g. recalibration of the test.

Up to 3 different controls for a single test can be displayed on the same chart. Each point on the chart represents one individual control result for a test plotted up to **3SD**

above or below the target mean. Points outside the **±3SD** range are plotted at the upper or the lower border of the chart.

Use the arrows at the top of the chart or the mouse to select individual points and display additional information about the point in the list above the chart. A vertical blue bar on the chart indicates the point has been accumulated. The vertical pink bar indicates the currently selected control.



If for one test different sample types are defined (**S. Type**), for example serum and urine, then the appropriate control within the **QC chart** based on the sample type must be selected.

Buttons

Comment Choose this button to display the **Comment** window. Used this window to enter a comment to the selected point and/or to exclude a point from the statistical calculation.

See *Comment window* on page E-325.

Select Choose this button to display the **Select Chart** window used to define up to 3 controls that are plotted on Levey Jennings Plot.

See *Select Chart window* on page E-326.

Comment window

➔ **QC** > **Individual** > **Chart** > **Comment**

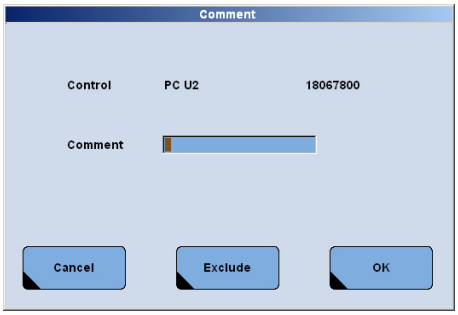


Figure E-196 Comment window

Use this window to enter a comment related to the currently selected QC point and/or to exclude it.

When results are excluded, the corresponding values are not used in statistical calculation.

Control This field displays the control name and the control lot number.

Comment Use this text box to enter a comment for the currently selected QC point. After a comment (up to 20 characters) was entered and the <Enter> key pressed, the **OK** button turns yellow. The entered comment is printed on the individual QC chart report.

A point with a comment appears black on the Levey-Jennings chart. If the point is excluded, the point appears gray.

Exclude Use this button to exclude the currently selected QC point from calculation after confirmation. If excluded, the value is not used in statistical calculations.

A point which has been excluded appears white on the Levey-Jennings chart. If the point also has a comment, the point appears gray.

Select Chart window

➔ **QC** > **Individual** > **Chart** > **Select**

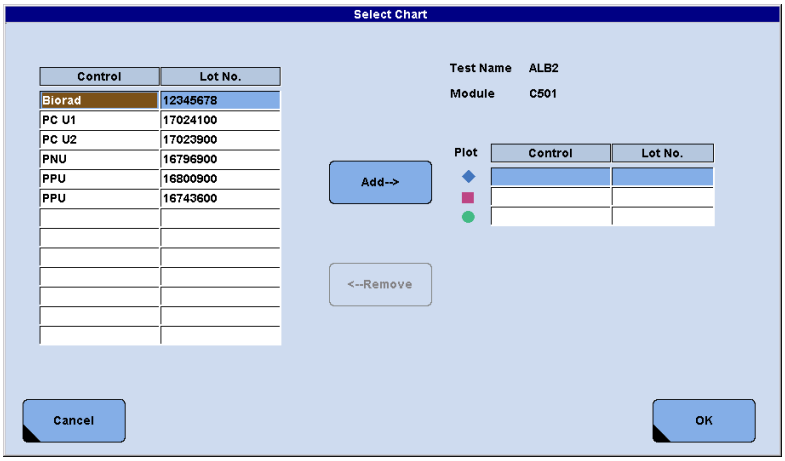


Figure E-197 Select Chart window

Use this window to assign controls to the symbols or to remove the assignment on the Levey-Jennings chart. Up to 3 different controls for a single test can be displayed on the same chart.

Control/Lot No. list Use this list on the left to select the control to be assigned to the symbol in the plot list.

Test Name This field displays the test name currently selected in the **Test Module** list box on **QC** > **Individual** > **Chart**.

Module This field displays the module and measuring channel on which the test was performed.

Plot list This list on the right displays which control is currently assigned to which symbol.

Plot: This column displays the symbol which appears on **QC** > **Individual** > **Chart** (◆, ■ or ●).

Control: This column displays the control name currently assigned to the symbol in the **Plot** column.

Lot No.: This column displays the lot number of the control currently assigned to the symbol in the **Plot** column.

Buttons

Add Use this button to assign the control currently selected in the **Control Lot No.** list to the currently selected symbol in the **Plot** list.

Remove Use this button to remove the control from the **Plot** list.

Realtime QC window

➔ **QC** > **Individual** > **Realtime QC**

This screen can be viewed by an operator with operator level, but a supervisor level (or higher) is required to edit the data.

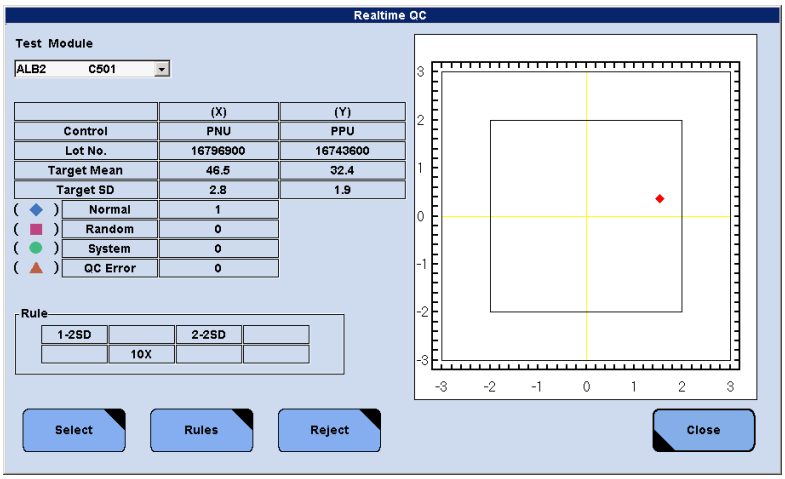


Figure E-198 Realtime QC window

Use this window to view a Yoden twin plot of the individual QC values for a test, to determine which 2 controls for the same test are evaluated by multi-rule Shewhart method and to reject QC results. The 2 controls can be compared against each other to give an indication of the consistency of measurement.

All paired QC results are checked by a multi-rule Shewhart method. When a random, systematic or indeterminate QC error is detected, an alarm is issued. This screen enables you to demonstrate that all reported results are properly controlled.

For more Information, see:
Configuring and using realtime QC on page B-212
Select Rules window on page E-332

The Yoden twin plot is displayed on the right side of the screen. The left side of the screen displays the selected controls and their respective mean and SD values. The number of points associated with each type of QC error is also displayed.

See *Yoden Twin Plot* on page E-328.

Test Module

Use this list box to select the test together with its associated module and measuring channel for which the realtime QC is to be displayed.

The area below the **Test Module** list box shows detailed data for the selected test/module detection combination for the 2 selected controls plotted on the X-axis and Y-axis. Each line can contain 2 values, 1 for **X** and 1 for **Y**.

To perform a realtime QC comparison of a control pair, the controls have to be placed right after each other for measurement and then measured consecutively.

Control

This line displays the 2 controls that are plotted on the X-axis and Y-axis. The controls displayed here can be selected on the **Select Control** window. To display this window choose **QC** > **Individual** > **Realtime QC** > **Select**.

See *Select Control window* on page E-331.

Lot No. This line displays the lot numbers of the controls for X and Y, as defined on **QC** > **Install**.

Target Mean This line displays the target mean of the corresponding control, as defined on **QC** > **Install**.

See *Install screen* on page E-344.

Target SD This line displays the target standard deviation (1 SD) of the corresponding control, as defined on the **QC** > **Install**.

See *Install screen* on page E-344.

Normal (◆) This line displays the number of points without QC errors. They are represented by the symbol (◆) on the plot.

The most recent pair of QC is displayed as a red diamond (◆) on the plot.

Random (■) This line displays the number of points with random errors. They are represented by the symbol (■) on the plot.

System (●) This line displays the number of points with system errors. They are represented by the symbol (●) on the plot.

QC Error (▲) This field displays the number of points with indeterminate QC errors. They are represented by the symbol (▲) on the plot.

If no rules are selected, then no random, systematic, or indeterminate errors are displayed or issued as a data alarm.

Rule area

This area displays the Shewhart rules and run size that are currently selected for the QC evaluation. These rules are selected on the **Select Rules** window. To display this window choose **QC** > **Individual** > **Realtime QC** > **Rules**.

See *Select Rules window* on page E-332.

Yoden Twin Plot

The Yoden twin plot displays 2 controls for each test. Each time the selected controls are run, the results are compared against their respective mean and standard deviation. The most recent pair of QC is displayed as a red diamond (◆) on the plot.

The multi-rule Shewhart rules must be selected, using the **QC** > **Individual** > **Realtime QC** > **Rules**, for the evaluation of the QC results.

Buttons

Select Choose this button to display the **Select Control** window. Use this window to determine which 2 controls are to be evaluated by multi-rule Shewhart and to assign the controls to the X-axis and Y-axis of the Yoden plot (administrator level).

See *Select Control window* on page E-331.

Rules Choose this button to display the **Select Rules** window. Use this window to select the rules to be used to evaluate the QC results (administrator level).

See *Select Rules window* on page E-332.

QC rules need to be selected prior to QC measurement in order to be applied to the QC measurement.

Reject Choose this button to display the **Reject Data** window. Use this window to reject QC data containing specific data alarms from the Yoden twin plot (Supervisor and administrator level).

See *Reject Data window* on page E-333.

Accumulate Data window

➔ **QC** > **Individual** > **Accumulate**

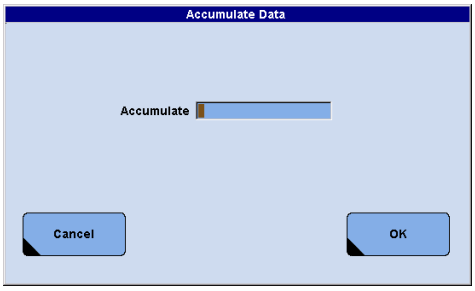


Figure E-199 Accumulate Data window - X-R

Use this window to accumulate a range of results selected on the **Individual QC** screen.

The selected results are accumulated depending on the method selected on the **QC Setting** window (**Utility** > **System** (**Page 1/4**) > **QC Setting**).

See *QC Setting window* on page E-387.

If **Mean-R** is set as accumulation method a confirmation window is displayed.

If **X-R** has been selected as the accumulation method, the **Accumulate** text box is available.

Accumulate Use this text box to enter the control-run result that is to be accumulated. For example, if the selected control has been measured 5 times and 3 is entered in this text box, only the result of the third run will be accumulated.

For more information, see:
Accumulation methods for QC measurement data on page B-199
Accumulation of QC results on page B-215

- Accumulated results are deleted from the **QC** > **Individual** screen, but they remain on the **Individual QC Chart** window highlighted in blue and also remain on **Workplace** > **Data Review** > **QC View** (select from **Data** area).
- If you delete the data on **Workplace** > **Data Review** > **QC View** (**Data** area) this also deletes all data from the **Individual QC Chart** window; all accumulated data remain.

Select Control window

➔ **QC** > **Individual** > **Realtime QC** > **Select**

This window can be accessed by an operator with administrator level only.

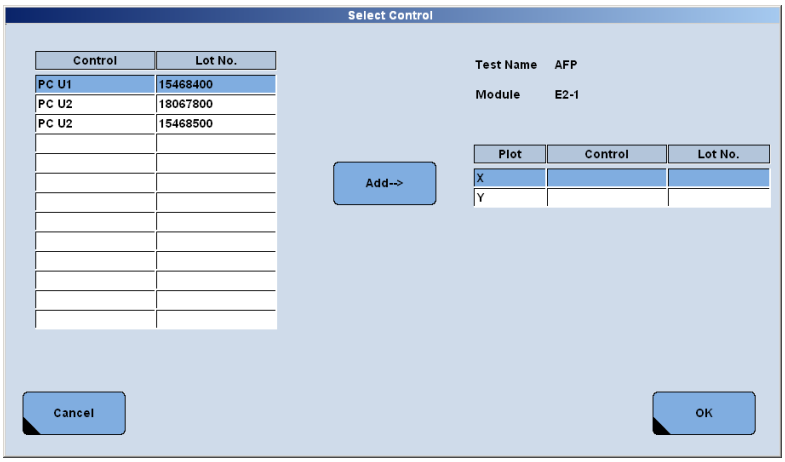


Figure E-200 Select Control window

Use this window to determine which 2 controls are evaluated by multi-rule Shewhart and to assign the controls to the X-axis and Y-axis of the Yoden plot.

Control/Lot No. list This list displays all available controls on the system together with their corresponding lot numbers. Select the control to be assigned to the X-axis or Y-axis from the list.

Control: This column displays the control name.

Lot No.: This column displays the control lot number.

Add--> Use this button to assign the control currently selected in the **Control/Lot No.** list to the axis currently selected in the **Plot** list. If the axis selected in the **Plot** list has a control already assigned, it will be replaced.

Test Name This field displays the test for which the 2 controls are being assigned as selected on **QC** > **Individual** > **Realtime QC**.

Module This field displays the analytical module the QC is performed on.

Plot list This list displays which controls are currently assigned to which axes.

Plot: This column displays **X** for the X-axis and **Y** for the Y-axis.

Control: This column displays the control name assigned to the corresponding axis.

Lot No.: This column displays the lot number for the controls assigned to the corresponding axis.

Select Rules window

➔ **QC** > **Individual** > **Realtime QC** > **Rules**

This window can be accessed by an operator with administrator level only.

Use this window to select the rules used to evaluate the QC results.

The multi-rule Shewhart method uses a Westgard algorithm. This algorithm applies the set of rules selected in this window. A pair of controls for each application is compared against a known standard deviation and mean. In some cases, only 1 of the controls (**X** or **Y**) may fail the test applied by the rule. When a control sample fails a test, a data alarm is issued and the plot on **QC** > **Individual** > **Realtime QC** displays a symbol that corresponds to the type of QC error detected.

For information about QC rules, refer to the COBI CD.

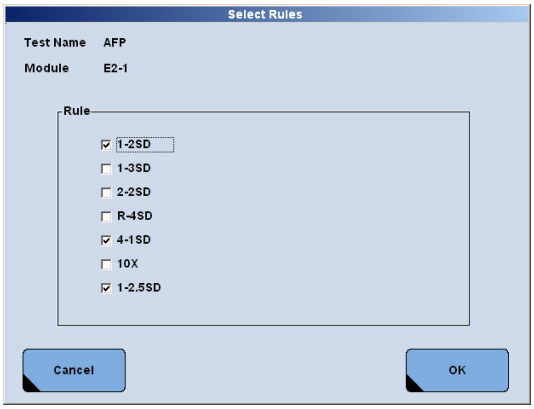


Figure E-201 Select Rules window

Test Name This field displays the test to which the rules shall apply, as selected on the **QC** > **Individual** > **Realtime QC**.

Module This field displays the module the QC is performed on. For the **e** 601 the measuring channel is also displayed.

Rule area Use this area to select the Shewhart rules by means of 7 check boxes. Any combination of the check boxes can be selected. The different Shewhart rules are **1-2SD**, **1-3SD**, **2-2SD**, **R-4SD**, **4-1SD**, **10X** and **1-2.5SD**.

Run Size If the **R-4SD** rule is selected, a **Run Size** text box is enabled in which the run size can be entered (1 to 10). This number determines how many successive control measurements for control X and control Y are monitored and evaluated according to the R-4SD rule.

See *Configuring and using realtime QC* on page B-212.

If R-4SD is selected, the run size must be defined in the Run Size text box.

Reject Data window

➔ **QC** > **Individual** > **Realtime QC** > **Reject**

This window can be accessed by an operator with supervisor (or higher) level only.

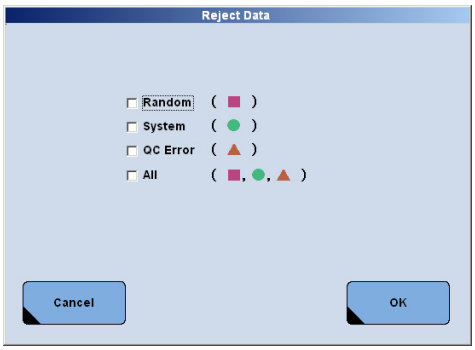


Figure E-202 Reject Data window

Use this window to reject realtime QC results containing specific data alarms from the Yoden twin plot. This result is deleted from the plot.

Random (■) Select this check box to mark all realtime QC results with a random error for deletion.

System (●) Select this check box to mark all realtime QC results with a system error for deletion.

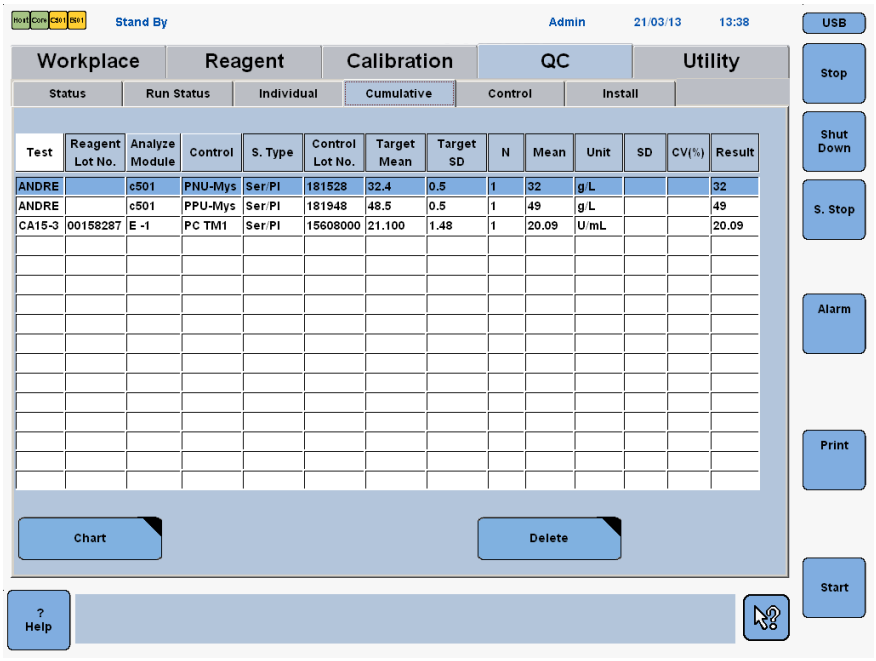
QC (▲) Select this check box to mark all realtime QC results with an indeterminate QC error for deletion.

ALL (■, ●, ▲) Select this check box to mark all realtime QC results with any errors (random, system or indeterminate) for deletion.

OK Use this button to delete the selected realtime QC results after confirmation.

Cumulative screen

➔ **QC** > **Cumulative**



Test	Reagent Lot No.	Analyze Module	Control	S. Type	Control Lot No.	Target Mean	Target SD	N	Mean	Unit	SD	CV(%)	Result
ANDRE		c501	PNU-Mys	Ser/Pl	181528	32.4	0.5	1	32	g/L			32
ANDRE		c501	PPU-Mys	Ser/Pl	181948	48.5	0.5	1	49	g/L			49
CA15-3	00158287	E -1	PC TM1	Ser/Pl	15608000	21.100	1.48	1	20.09	U/mL			20.09

Figure E-203 Cumulative screen

On this screen you can see a statistical evaluation and overview of accumulated control results for all modules, tests and control measured on the system. Use this screen to view a list of all accumulated QC results, to display the Levey-Jennings chart for accumulated QC points, and to delete accumulated data.

For more Information, see:
Accumulation of QC results on page B-215
Excluding an individual QC point or adding a comment on page B-211
QC Cumulative screen on page B-217

Cumulative list

This list displays information for all accumulated QC results. It can be sorted by test name, module or control name. A white background distinguishes the selected column tab.

- The width of the individual columns can be varied by clicking on the column dividers in the list box header and dragging them to the left or right.
- Most information of the control, displayed in the different columns, are defined on the **QC** > **Install** screen (for example control name, sample type, control lot number).

See *Install screen* on page E-344.

Test The **Test** column displays the short name of the test.

*Reagent Lot No. (**e** 601)* The **Reagent Lot No.** column displays the lot number of the reagent pack used for the QC measurement on **e** 601. The reagent pack lot number is only given for Roche controls.

Analyze Module The **Analyze Module** column displays the module name on which the QC result was measured. For the **e** 601 the two measuring cells are distinguished.

Control The **Control** column displays the name of the used control.

S. Type The **S. Type** column displays the sample type defined for the control (**Ser/Pl**, **Urine**, **CSF**, **Suprnt** or **Other**).

Control Lot No. The **Control Lot No.** column displays the control lot number.

Target Mean The **Target Mean** column displays the control target mean for the test.

Target SD The **Target SD** column displays the control target standard deviation for the test.

N The **N** column displays the number of accumulations (maximum of 500).

Mean The **Mean** column displays the accumulated mean for each test. The accumulation method is selected on **Utility** > **System** (**Page 1/4**) > **QC Setting**.

See *QC Setting window* on page E-387.

Unit The **Unit** column displays the unit of the test as defined on **Utility** > **Application** > **Range**.

SD The **SD** column displays the standard deviation calculated from N accumulations for the corresponding test.

CV(%) The **CV(%)** column displays the coefficient of variation calculated from the mean value and the standard deviation for the corresponding test.

Result The **Result** column displays the most recent accumulated mean value.

Buttons

Chart Choose this button to display the **Cumulative QC Chart** window, where the Levey-Jennings chart is displayed, showing accumulated QC points for each test.

See *Cumulative QC Chart window* on page E-336.

Delete Use this button to delete the selected cumulative QC data after confirmation (supervisor level).

Cumulative QC Chart window

➔ **QC** > **Cumulative** > **Chart**

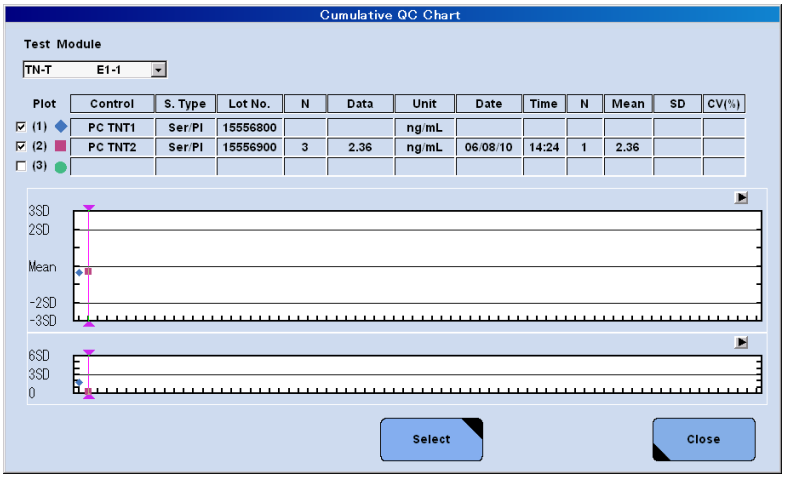


Figure E-204 Cumulative QC Chart window

Use this window to view the Levey-Jennings chart for accumulated QC points of the test.

See *Levey-Jennings chart* on page E-338.

Depending on the **QC Setting** on **Utility** > **System** (**Page 1/4**) > **QC Setting** > **Range Plot** check box the chart looks different. The range plot shows the range between the accumulated data.

If no controls are displayed in the chart, you have to select controls on the **Select Chart** window.

See *Select Chart window* on page E-326.

Test Module list box Use this list box to select the test/module combination for which results are to be displayed.

Chart list

This list displays detailed information for the point currently selected in the Levey-Jennings chart.

Plot This column displays 3 check boxes for different controls: **(1)**, **(2)**, and **(3)**. Any combination of them can be selected to display the corresponding data on the chart.

- Control (1)
- Control (2)
- Control (3)

Control The **Control** column displays the control name and graphic symbol associated with the different controls. The controls are represented by the following graphic symbols:

The 3 controls available are selected on **QC** > **Cumulative** > **Chart** > **Select**.

S. Type The **S. Type** column displays the sample type of the control.

Lot No. The **Lot No.** column displays the lot number of the control.

N The **N** column displays the number of control results that were accumulated for the selected point on the chart.

Data The **Data** column displays the value of the currently selected point in the chart.

Unit The **Unit** column displays the unit of measure of the currently selected point in the chart.

Date The **Date** column displays the date when the selected point was accumulated.

Time The **Time** column displays the time of the accumulated point that is selected in the chart.

N The **N** column displays the number of accumulations.

Mean The **Mean** column displays the calculated mean of all accumulations for the currently selected test and control combination.

SD The **SD** column displays the standard deviation for all accumulations for the corresponding test. The SD is calculated from N accumulations for the test.

CV(%) The **CV(%)** column displays the coefficient of variation for all accumulations for the corresponding test. It is calculated from the mean value and the standard deviation for the test.

Levey-Jennings chart

Up to 3 different controls for a single test can be displayed on the same chart. Each point on the chart represents one individual control result for a test plotted up to **3SD** above or below the mean. Points outside the **±3SD** range are plotted at the upper or the lower border of the chart

Use the arrows at the top of the chart or the mouse to select individual points and display additional information about the point in the list box above the chart. The vertical pink bar indicates the currently selected control.

The range plot in the lower part of the chart displays the average deviation of the means of the accumulated points.



The range plot is only displayed if it is activated under **Utility** > **System** > **QC Setting**.

Button

Select Choose this button to display the **Select Chart** window used to define up to 3 controls that are plotted on Levey Jennings Plot.

See *Select Chart window* on page E-339.

Select Chart window

➔ **QC** > **Cumulative** > **Chart** > **Select**

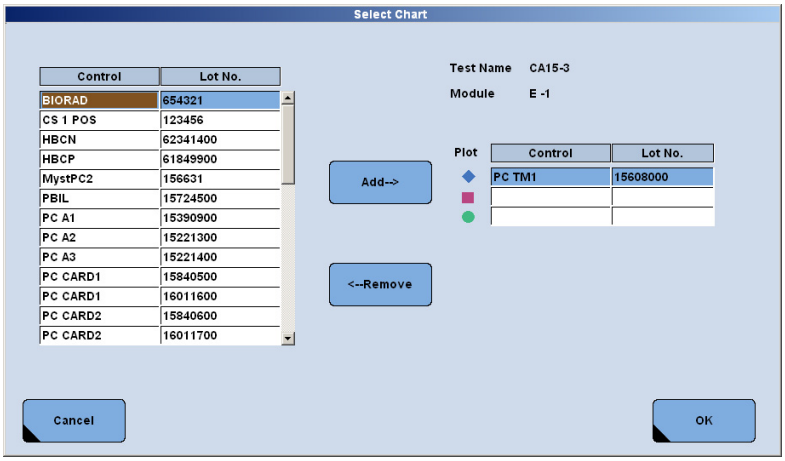


Figure E-205 Select Chart window

Use this window to assign controls to the symbols or to remove the assignment on the Levey-Jennings chart. Up to 3 different controls for a single test can be displayed on the same chart.

Control Lot No. list Use this list on the left to select the control to be assigned to the symbol in the plot list.

Test Name This field displays the test name currently selected in the **Test Module** list box on **QC** > **Cumulative** > **Chart**.

Module This field displays the module and measuring channel on which the test was performed.

Plot list This list on the right displays which controls are currently assigned to which symbol.

Plot: This column displays the symbol which appears on **QC** > **Cumulative** > **Chart** (◆, ■ or ●).

Control: This column displays the control name currently assigned to the symbol in the **Plot** column.

Lot No.: This column displays the lot number of the control currently assigned to the symbol in the **Plot** column.

Buttons

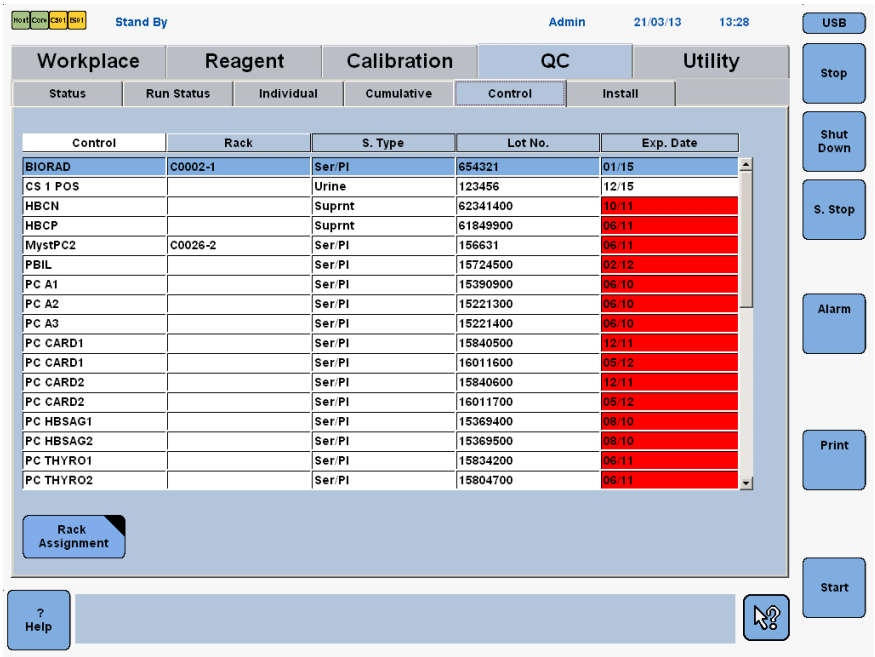
Add Use this button to assign the control currently selected in the **Control Lot No.** list to the currently selected symbol in the **Plot** list.

Remove Use this button to remove the control from the **Plot** list.

Control screen

➔ **QC > Control**

This screen can be viewed by an operator with operator level, but a supervisor level (or higher) is required to edit the data.



Control	Rack	S. Type	Lot No.	Exp. Date
BIORAD	C0002-1	Ser/Pl	654321	01/15
CS 1 POS		Urine	123456	12/15
HBCN		Suprnt	62341400	10/11
HBCP		Suprnt	61849900	06/11
MystPC2	C0026-2	Ser/Pl	156631	06/11
PBIL		Ser/Pl	15724500	02/12
PC A1		Ser/Pl	15390900	06/10
PC A2		Ser/Pl	15221300	06/10
PC A3		Ser/Pl	15221400	06/10
PC CARD1		Ser/Pl	15840500	12/11
PC CARD1		Ser/Pl	16011600	05/12
PC CARD2		Ser/Pl	15840600	12/11
PC CARD2		Ser/Pl	16011700	05/12
PC HBSAG1		Ser/Pl	15369400	08/10
PC HBSAG2		Ser/Pl	15369500	08/10
PC THYRO1		Ser/Pl	15834200	06/11
PC THYRO2		Ser/Pl	15804700	06/11

Figure E-206 QC > Control screen

Use this screen to view the installed controls including the lot number and their expiration date. The system can handle up to 5 different lots of the same control. Here you can also view and change the assigned control rack numbers and positions for non-barcoded controls.

Do not mix barcoded and non-barcoded control vials in one rack. If on a rack with position assignment a barcoded control is placed the rack will not be processed.

Control list The control list displays the control name, the rack number and position to which the control is assigned, sample type, lot number and expiration date. It can be sorted by control name or rack number by using the corresponding tabs.

Control The **Control** column displays the control name.

Rack The **Rack** column displays the rack number and the position of the control within the rack (e.g., **C0123-3**, for control rack number C0123, position 3).

S. Type The **S. Type** column displays the sample type assigned to the control.

Lot No. The **Lot No.** column displays the lot number of the control.

Exp. Date The **Exp. Date** column displays the expiration date of the control. Expired controls have a red background.

Expired controls are still measured.

Button

Rack Assignment Choose this button to display the **QC Rack Assignment** window. Use this window to assign a position to a non-barcoded control (supervisor level).

See *QC Rack Assignment window* on page E-342.

QC Rack Assignment window

➔ **QC** > **Control** > **Rack Assignment**

This window can only be accessed by an operator with supervisor level or higher.

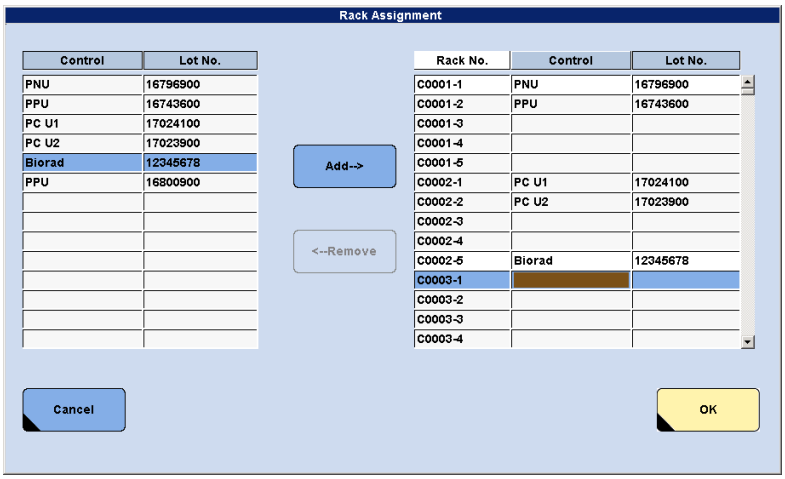


Figure E-207 QC Rack Assignment window

Use this window to assign a control to a rack position if the system is operating in non-barcode mode for controls. The barcode setting is made in **Utility** > **System** > **Barcode Setting** area.

For more information about position assignment, see *To assign a control to a specific rack and position* on page B-219.

Control list

Use this list, on the left of the window, to select the control to be assigned to the position selected in the rack list.

Control The **Control** column displays the name of the control.

Lot No. The **Lot No.** column displays the lot number of the control.

Rack list

Use this list, on the right of the window, to select a specific rack number and position. It can be sorted by rack number or control name.

Rack No. The **Rack No.** column displays the rack number and position (e.g., **C0016**-**4** for control rack number C0016, position 4).

Different designations for control racks

There are following designations for the control racks:

- Rack color: white
- Label on rack: Q001 - Q999
- Software displays: C00001 - C00999 or C0001 - C0999

Control The **Control** column displays the name of the control currently assigned to the rack number and position.

Lot No. The **Lot No.** column displays the lot number of the control assigned to the rack number and position.

Buttons

Add Choose this button to assign the highlighted control from the control list on the left to the selected rack number and position on the right. This button is only active if an empty rack number and position is selected from the rack list.

Remove Choose this button to delete the control from the selected rack number and position. This button is only active when a selected rack number and position have a control assigned.

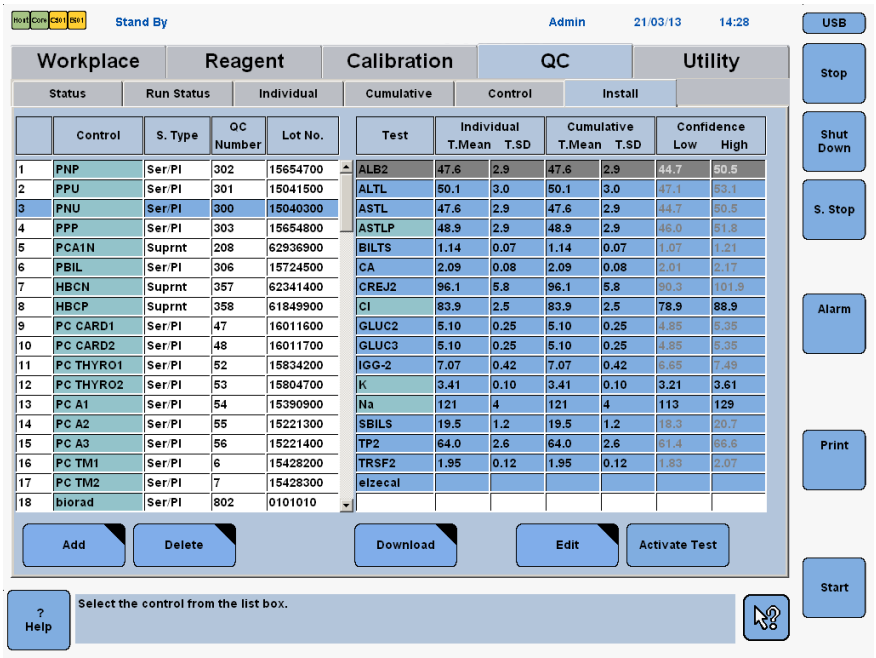
A control can be assigned to more than one position on different racks.

If the control is assigned to several positions on one rack, tests will be measured according to the request only once. But the instrument will change over to the next position, if the volume is insufficient for all requests in the first pipetted position. The change over is not triggered by a sample short detection, but by the internal volume calculation.

Install screen

➔ **QC > Install**

This screen can be accessed by an operator with supervisor level or higher.



	Control	S. Type	QC Number	Lot No.
1	PNP	Ser/Pl	302	15654700
2	PPU	Ser/Pl	301	15041500
3	PNU	Ser/Pl	300	15040300
4	PPP	Ser/Pl	303	15654800
5	PCA1N	Suprnt	208	62936900
6	PBIL	Ser/Pl	306	15724500
7	HBCN	Suprnt	357	62341400
8	HBCP	Suprnt	358	61849900
9	PC CARD1	Ser/Pl	47	16011600
10	PC CARD2	Ser/Pl	48	16011700
11	PC THYRO1	Ser/Pl	52	15834200
12	PC THYRO2	Ser/Pl	53	15804700
13	PC A1	Ser/Pl	54	15390900
14	PC A2	Ser/Pl	55	15221300
15	PC A3	Ser/Pl	56	15221400
16	PC TM1	Ser/Pl	6	15428200
17	PC TM2	Ser/Pl	7	15428300
18	biorad	Ser/Pl	802	0101010

Test	Individual T.Mean	Individual T.SD	Cumulative T.Mean	Cumulative T.SD	Confidence Low	Confidence High
ALB2	47.6	2.9	47.6	2.9	44.7	50.5
ALTL	50.1	3.0	50.1	3.0	47.1	53.1
ASTL	47.6	2.9	47.6	2.9	44.7	50.5
ASTLP	48.9	2.9	48.9	2.9	46.0	51.8
BILTS	1.14	0.07	1.14	0.07	1.07	1.21
CA	2.09	0.08	2.09	0.08	2.01	2.17
CREJ2	96.1	5.8	96.1	5.8	90.3	101.9
Cl	83.9	2.5	83.9	2.5	78.9	88.9
GLUC2	5.10	0.25	5.10	0.25	4.85	5.35
GLUC3	5.10	0.25	5.10	0.25	4.85	5.35
IGG-2	7.07	0.42	7.07	0.42	6.65	7.49
K	3.41	0.10	3.41	0.10	3.21	3.61
Na	121	4	121	4	113	129
SBILS	19.5	1.2	19.5	1.2	18.3	20.7
TP2	64.0	2.6	64.0	2.6	61.4	66.6
TRSF2	1.95	0.12	1.95	0.12	1.83	2.07
elzecal						

Figure E-208 Install screen

Use this screen to download, edit, add and delete controls from the system and to activate or change control values or to activate or deactivate tests for the controls.

For more information, see:
QC Install screen on page B-220
Downloading control data on page B-221
Editing control values on page B-224
Updating of control values on page B-225
Activating control tests on page B-227

Control list

The list, on the left displays all controls that are installed on the system. For all installed controls the control name is highlighted in green. Up to 100 controls can be installed on the system. Up to 5 different lots of the same control can be installed on the system.

If a second lot of the same control is downloaded the settings of the previous installed lot are taken over to the new lot.

Control The **Control** column displays the name of the control.

S. Type The **S. Type** column displays the sample type assigned to the control.

QC Number The **QC Number** column displays the material code for the control.



The material code range from 001 to 800 is for Roche controls, whereas the range from 801 to 999 is for Non-Roche controls.

Lot No. The **Lot No.** column displays the lot number of the installed control.

Test list

This list, on the right of the window, displays details about the tests assigned to the control selected from the control list on the left. Tests with a green background are activated for this control to be measured on the system. Tests with a blue background are not activated and will not be measured for this control. If a test is not activated, the corresponding entry in the **Control > Status** screen is not available for QC selection.

Test The **Test** column displays the test name.

Individual T. Mean and T. SD The **Individual T. Mean** and **T. SD** columns display the individual target mean and standard deviation values as downloaded, or manually edited in **QC** > **Install** > **Edit**.

Cumulative T. Mean and T. SD The **Cumulative T. Mean** and **T. SD** columns display the cumulative target mean and standard deviation values as downloaded, or manually edited in **QC** > **Install** > **Edit**.

Confidence Low and High The **Confidence Low** and **High** columns display the lower and upper confidence limits as downloaded, or edited in **QC** > **Install** > **Edit**. The numbers are grayed out if the selected test is not configured for QC Violation or if it does not use the control selected from the control list on the left.

For more information, see:
Edit Control window on page E-351
Calib. (photometric tests) on page E-496

Buttons

Add Choose this button to display the **Add Control** window to manually add a control to the system and edit control details. This manually added control must be defined as a Non-Roche control with a material code number between 801 and 999.



For Roche controls, only the name can be edited.

See *Add Control window* on page E-347.

Delete Use this button to delete the selected control(s) after confirmation.

Download Choose this button to display the **Download** window used to download new control data from **cobas** link.

See *Download window* on page E-348.

Edit Choose this button to display the **Edit Control** window used to change target values for a test for the selected control.

See *Edit Control window* on page E-351.

Activate Test/Inactivate Test Use this button to activate/inactivate the selected test for the selected control. This button toggles between **Activate Test** and **Inactivate Test** depending on the operator selection. Tests with a green background are activated for this control to be measured on the system. Tests with a blue background are not activated and will not be measured for this control. You can select several tests at a time to activate them.



To activate a test for Non-Roche controls, the test must have the target mean and SD defined. Select the test prior to choosing the **Activate Test** button.

For more information, see *Activating control tests* on page B-227.

Add Control window

➔ **QC** > **Install** > **Add**

This window can be accessed by an operator with supervisor level or higher.

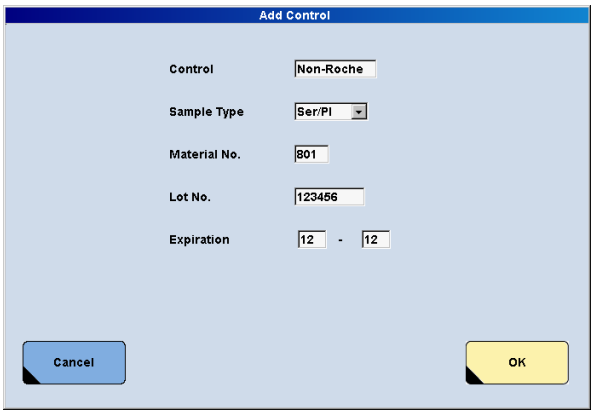


Figure E-209 Add Control window

Use this window to add a Non-Roche control to the system or edit the name of a registered Roche control.

For more information about adding controls, see:
To add controls manually on page B-223
Activating control tests on page B-227

- If a line already assigned to a Roche control is selected, it is possible to edit the current name. No other details can be edited.
- Choose an empty position in the control list to add a control manually.

Control Use this text box to enter the control name (up to 10 characters).

Sample Type Use this list box to select the sample type (**Ser/PI, Urine**, **CSF**, **Suprnt** or **Other**) to be associated with the control.

Material No. Use this text box to enter the material code for the control (3 digits).

The material code range from 001 to 800 is for Roche controls, whereas the range from 801 to 999 is for Non-Roche controls.

Lot No. Use this text box to enter the control lot number (up to 8 characters).

Expiration Use these 2 text boxes to define the expiration date for the control. The first text box is used for the year, and the second is used for the month (1 to 12).

Expired controls are still measured.

Download window

➔ **QC** > **Install** > **Download**

This window can be accessed by an operator with supervisor (or higher) level password only.

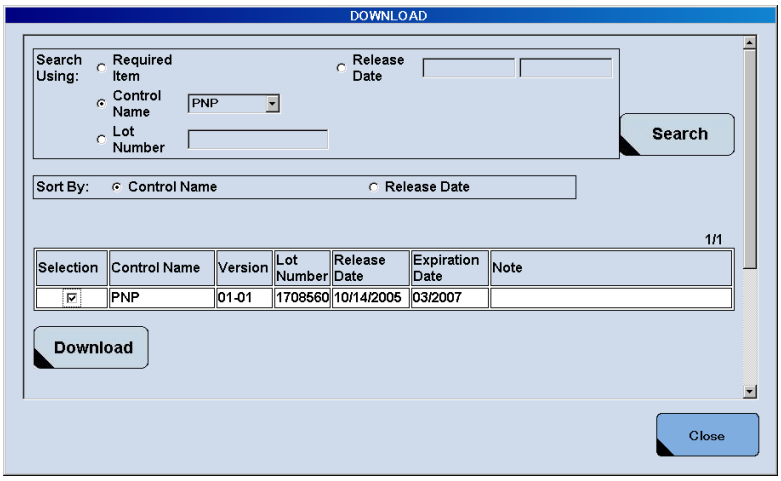


Figure E-210 Download window

Use this window to search for control data on **cobas** link. In case a control name already exists use this window to confirm overwriting the control information already stored for this control name.

No update of manually edited control values

In case a value has been manually edited, this value will not be updated when you download new control values from **cobas** link. There is no indication in the software if the value was manually edited before.

- Check the control values after downloading.
- If you want to return to the original control value, delete the control and download it again from **cobas** link. Perform control measurement before you resume routine operation.

Search Using area

Required Item An item has not been found in the instrument at the time of barcode reading. Parameters necessary for measurements must be downloaded.

Release Date Use this item to display the controls on **cobas** link sorted by the latest release date.

Control Name In this drop down list the control name can be selected and after pressing **Search** all available lots of this control are listed below.

Lot Number In this text field the lot number of the control can be entered. The lot number must always be entered with 8 digits. The last two digits are zeros.

Search Use this button to search and list the control parameters below.

After a successful search a table appears in the lower half of the window. This table displays all controls that match the search criteria.

Sort By area

Use this function to sort the control list by control name or release date.

Control Name Use this function to sort the control list by control name.

Release Date Use this function to sort the control list by release date.

Download area

Use this area to select the desired item for download.



Download latest version

Always download the latest version of control data. Select **Release Date** in the **Sort By** area to change the display order and select the control data with the latest **Release Date**.

[Next>] Choose [**Next >**] to display more search results.

Page/pages Depending on the number of items in the table there can be more than one page. For example, the information **2/3** means that page 2 of 3 is displayed.

Selection This check box has to be activated to define which information should be downloaded.

Control Name This column displays the name of the control.

Version This column displays the version number of the downloaded control information. If the control target value is changed, a new version number is available. Make sure to download always the latest version.

Lot Number This column displays the lot number of the control.

Release Date This column displays when the information was released by Roche.

Expiration Date This column displays the expiration date of the control.

Note In the column Note you can find additional information about the control.

Download Use this button to download the control parameters via **cobas** link to the system.

Edit Control window

➔ **QC > Install > Edit**

This window can be accessed by an operator with supervisor level or higher.

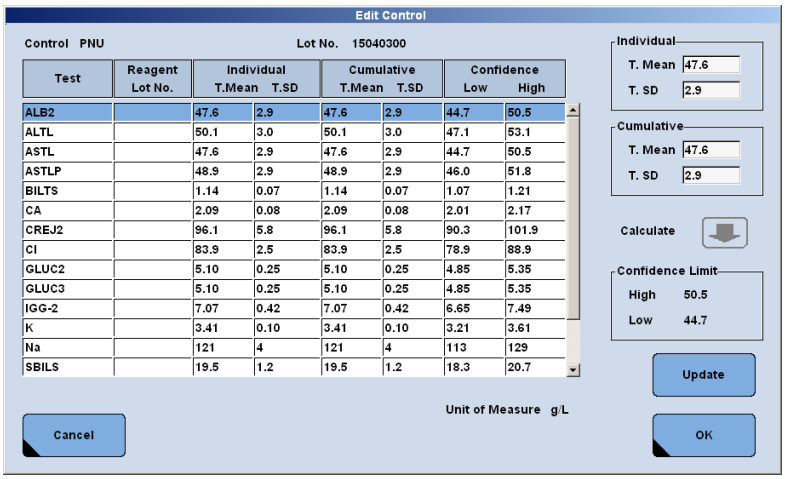


Figure E-211 Edit Control window

Use this window to define and edit target values and confidence limits for the tests and to recalculate the confidence limit if necessary.

No update of manually edited control values

In case a value has been manually edited, this value will not be updated when you download new control values from **cobas** link. There is no indication in the software if the value was manually edited before.

- Check the control values after downloading.
- If you want to return to the original control value, delete the control and download it again from **cobas** link. Perform control measurement before you resume routine operation.

Control This field displays the name of the control.

Lot No. This field displays the lot number of the control.

Test list

This list displays all tests linked to this control including the **cobas e** pack lot numbers (**e** 601), as well as individual and cumulative target mean, standard deviation and the confidence limit which is used if the test is activated for QC violation.

Test The **Test** column displays the test name.

Reagent Lot No. (e 601) The **Reagent Lot No.** column displays the **cobas e** pack lot number for **e** 601 tests.

Individual T.Mean / T.SD The **Individual T.Mean / T.SD** column displays the individual target mean and target SD downloaded from **cobas** link or previously assigned.

Cumulative T.Mean / T.SD The **Cumulative T.Mean / T.SD** column displays the cumulative target mean and target SD downloaded from **cobas** link or previously assigned.

Confidence High / Low The **Confidence High / Low** column displays the upper and lower confidence limits which will be used to evaluate the control if the test is activated for QC violation.

Unit of Measure This field displays the unit which is used for the test as defined under **Utility** > **Application** > **Range**.

Individual and Cumulative areas

Individual area The values displayed or entered in the **Individual** area correspond to the selected test in the test window and also to the target values on the **QC** > **Individual** screen.

T. Mean Use the **T. Mean** text box to enter a target value for the selected test.

T. SD Use the **T. SD** text box to enter a standard deviation (1 SD) for the selected test.

Cumulative area The values displayed or entered in the **Cumulative** area correspond to the test in the selected test list and also to the target values on the **QC** > **Cumulative** screen.

T. Mean Use the **T. Mean** text box to enter a cumulative target value for the selected test.

T. SD Use the **T. SD** text box to enter cumulative standard deviation (1 SD) for the selected test.

Confidence Limit area

Confidence limits are automatically calculated whenever target and SD values are downloaded. In case target and SD values are entered manually (for example, for Non-Roche controls) the calculation of confidence limits is achieved by choosing the **Calculate** button.

High The **High** box displays the upper confidence limit of the selected test. This box is not an entry box if the concerned test is not configured for QC Violation (on **Utility** > **Application** > **Calib**.) or if it does not use the control which is currently being edited.

Low The **Low** box shows the lower confidence limit of the selected test. This box is not available if the concerned test is not configured for QC Violation.

Buttons

Calculate Use this button to calculate the confidence limits whenever the QC target value or SD is edited or entered manually. This button is not available if the concerned test is not configured for QC Violation (on **Utility** > **Application** > **Calib.**).

For more information, see:
To activate QC violation on page B-265
To edit control values on page B-224

Update Use this button when it is yellow to update the data list with the new values. After updating values, the **OK** button turns yellow. To save the changes press the yellow **OK** button. The button turns blue.

Edit Control window

Utility menu

This chapter provides information about the **Utility** menu and the windows accessed from it. System and application parameters can be set in the **Utility** menu. In addition, maintenance functions, such as pipes, as well as the individual maintenance actions can be accessed from this menu.

In this chapter *Chapter* 27

System screen E-361
Rack Assignment area E-362
Barcode Setting area E-362
Printer Setting area E-362
Date and Time Setting area E-362
Other Setting area E-363
Analyzer Setting area E-363
Wash Rack Sampling E-364
Buttons E-364
Rack Assignment window E-367
Standard Tube tab E-368
Non Standard tab E-369
Non-Standard Tube area E-370
False Bottom Tube Rack area E-370
Module Setting tab E-371
False bottom/Cup on non-standard tube Setting window E-372
Barcode Setting window E-373
Alarm Setting window E-374
Host Communication Setting window E-376
Communication Setting E-376
RS232C Setting area E-377
Text Setting E-378
Button E-380
Result Upload Setting E-380
Host Test Code Setting window E-382
Test list E-382
Other elements E-382
Comment Title window E-383
Key Setting window E-384

Buttons E-384
Key Setting window E-385
Profile Setting window E-386
Buttons E-386
QC Setting window E-387
Reagent Level Check window E-388
Yellow Alarm area E-389
Test list E-389
Filter area E-389
Activate Alarm E-390
Purple Alarm area E-390
Test list E-390
Filter area E-391
Activate Alarm E-391
Calibration Mask Setting window E-392
Maintenance Setting window E-393
Edit Maintenance Type window E-394
Buttons E-395
User Definable window E-396
Maintenance Pipe Setting window E-397
Buttons E-397
Edit Pipe window E-398
Buttons E-399
Power Up Pipe Setting window E-400
Operator ID Setting window E-402
Buttons E-402
Add Operator ID window E-403
Overview of access levels E-403
Main screens E-404
Global screens E-409
Check Digit window (barcode mode) E-410
ISE Calibration Setting window E-411
Rack Delivery window E-412
Rack Reception Mode E-413
Dilution and Cleaner Cassette Setting window (c 501) E-415
Table List E-415
Reagent Information Area E-416
Button E-416
Bottle Setting window E-417
Bottle area E-417
Automatic Printout Setting window E-418
Review By Exception window E-419
Maintenance screen E-420
Buttons E-421
Maintenance Monitor window E-422
Maintenance items E-423
Reset window E-424
Rack Reset window E-425
Photometer Check window E-426
Cell Blank Measurement window E-427

Incubation Water Exchange window E-428
Air Purge window E-429
Wash Reaction Parts window E-430
Reagent Prime window E-431
ISE area E-432
Elecsys area E-432
Cell Detergent Prime window E-433
Incubator Bath Cleaning window E-434
IS Bath Cleaning window E-435
Sample Probe Wash window E-436
Motor off window E-437
Floppy Disk Utility window E-438
Parameter Read/Write window E-439
Media area E-439
Function area E-440
Test Count Write window E-441
Media area E-441
QC Timer Reset window E-442
Probe Check window E-443
System Wash window E-444
Reagent Probe Wash window E-445
Bead Mixer Rinse window E-446
E module Reagent Wash window E-447
Pipetter Air Purge window E-448
Sipper Air Purge window E-449
Channel area E-449
MC Preparation window E-450
Channel area E-450
MC Exchange window E-451
Channel area E-451
Liquid Flow Path Cleaning window E-452
Channel area E-452
Inventory Update window E-453
Manual Cleaning window E-454
Pre-wash Sipper Rinse window E-455
Pre-wash Sipper Air Purge window E-456
Finalization window E-457
Channel area E-457
Empty PC/CC Reservoir window E-458
Initial Bead Mixing window E-459
Reagent Capping window E-460
AssayCup Discarding window E-461
System Air Purge (E Module) window E-462
Channel area E-462
System Prime (E Module) window E-463
Change Light Source Lamps window E-464
Trace Doc Export window E-465
Maintenance checks E-466
Check Disk window E-466
Media area E-467

Mode area E-467
Backup Data File E-467
Software information E-467
ISE Check window E-468
Mechanism Check window E-469
Sample Barcode Reader Check window E-470
Reagent Barcode Reader Check window E-471
Cassette Loading Check window E-472
Cuvette Mixing window E-473
Reagent Short Sensor Check window E-474
Sample Pipetting Check window E-475
Reagent Pipetting Check window E-476
Cap Opener Check window E-477
Bead Mixer Check window E-478
Gripper Check window E-479
Magazine Exchange Check window E-480
Sipper Check window E-481
Sipper area E-481
Pre-wash Probe Check window E-482
Pre-wash Gripper Check window E-483
Application screen E-484
Test list E-484
Analyze (c 501, photometric tests) E-486
Sample Volume area E-487
Dilution area E-488
Prozone Limit E-488
Miscellaneous fields E-488
Cassette Configuration area (c 501 (P)) E-489
Analyze (serum indexes) E-490
Factor area E-491
Qualitative area E-491
Analyze (e 601 tests) E-492
Default Dilution Ratio area E-493
Cap Open/Close Mode area E-493
Calib. (c 501 (ISE) tests) E-494
Timeout E-495
QC Violation E-495
Calib. (photometric tests) E-496
Calibration Type area E-497
Calibration checks limits E-497
Auto Calibration area E-498
Timeout E-498
Changeover E-499
QC Violation E-499
Calib. (e 601 tests) E-500
Auto Calibration area E-501
Timeout E-501
QC Violation E-502
Range (c 501 ISE and photometric tests) E-503
Qualitative area E-505

Expected Values area E-506
Default area E-506
Range (e 601 tests) E-507
Expected Values area E-509
Default area E-509
Other (c 501 ISE tests) E-510
Other (c 501 photometric tests) E-512
Application Parameter Delete window E-514
Download window E-515
Search Using area E-516
Sort By area E-516
Download area E-517
Confirmation window E-518
Calculated Test screen E-520
Calculated Test area E-521
Buttons E-521
Compensated Test area E-521
Buttons E-522
Calculated Test Formula window E-523
Formula tab E-524
Calculator and Test areas E-524
Range tab E-525
Expected Values area E-526
Default area E-526
Compensated Test Formula window E-527
Calculator and Test areas E-527
Special Wash screen E-528
Chemistry screen E-529
Reagent Probe area E-529
Cell area E-530
Sample Probe area E-531
Edit Reagent Probe Wash window E-532
Probe area E-532
From Reagent area E-532
To Reagent area E-532
Detergent area E-532
Edit Cell Wash window E-533
R1 area E-533
R2 area E-534
Edit Sample Probe Wash window E-535
Immune screen E-536
Reagent Probe E-536
Buttons E-537
Sample Probe for Chemistry E-537
Buttons E-537
Edit Reagent Probe Wash window E-538
From Reagent E-538
To Reagent E-538
Edit Sample Carry Over Evasion window E-539
Report Format screen E-540

Character Line Column list E-541
Print Order area E-543
Module Set screen E-544
Test Assignment E-545
c501 Test Assignment(C Module) E-546
e601 Test Assignment(E Module) E-547
Module Setting E-549

System screen

➔ **Utility** > **System**

This screen can be accessed by an operator with administrator level or higher.

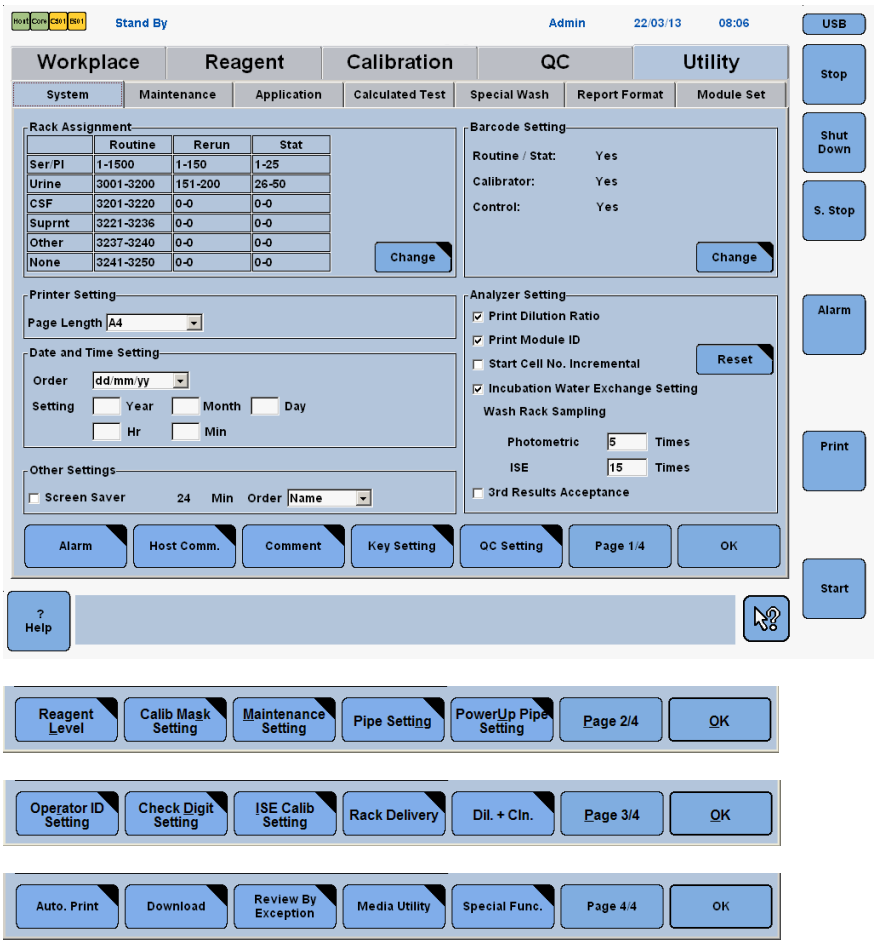


Figure E-212 System screen, page 1/4 and function buttons of pages 2, 3 and 4

The **System** screen has 4 pages of function buttons. The **Page** button is located in the lower right of the screen and is used to successively view each of these pages.

This screen is used to define system parameters.

Rack Assignment area

The **Rack Assignment** area displays information about the rack ranges and types assigned to the samples. The first column displays the sample types, followed by routine, rerun and STAT rack number ranges assigned to each sample type.

Change Choose the **Change** button in the **Rack Assignment** area to change rack ranges and tube types.

See *Rack Assignment window* on page E-367.

Barcode Setting area

Routine / Stat, Calibrator, Control These fields are displayed if the barcode mode is active.

If the **Barcode Setting** field displays **Yes**, barcode mode is used for this sample type. If the **Barcode Setting** field displays **No**, non-barcode mode is used for this sample type.

Change Choose **Change** to change between barcode and non-barcode modes.

See *Barcode Setting window* on page E-373.

Printer Setting area

Page Length Use this list box to select the page size for all printouts. Possible selections are **8 1/2" x 11"** and **A4** (21 cm x 29.7 cm).

Date and Time Setting area

Order Use this list box to select the date format used by the system. The following formats can be selected: **dd.mm.yy**, **mm.dd.yy**, **yy.dd.mm**, **yy.mm.dd** (d = day digit, m = month digit, y= year digit). The set format is used for all screen displays and printouts. For example, if the option **mm.dd.yy** (month, day, year) is selected, the 28th of June 2002 is displayed or printed in the format: 06/28/02.

Setting Use these text boxes to define the date and time. Valid values for **Year** ranges are from 80 to 99 for the years 1980 to 1999 and 00 to 35 for the years 2000 to 2035. The time is entered in 24 hour format, valid values for **Hr** range from 0 to 23.



If date or time is changed it is recommended to shutdown and restart the system to synchronize the new date and time with the information of the core processor.

Other Setting area

Screen Saver Select this check box to enable, or deselect the screen saver. If selected, the **Min** text box is available.

Min Enter the number of minutes after which the screen saver should be activated. The screen saver is automatically activated if no activity has occurred for the specified time interval.

Order Use this list box to select the order in which tests are listed on different screens, for example on the **Data Review** screen.

- Select **Name** to sort the tests in alphabetical order according to the test name.
- Select **Test No.** to sort the tests in the sequence in which they are displayed on the **Utility** > **Application** screen.

Analyzer Setting area

Choose this area to select whether information about the dilution ratio and module ID is to be included in data monitor reports.

Print Dilution Ratio Select the **Print Dilution Ratio** check box to print the applied dilution ratios on reports.

Print Module ID Select the **Print Module ID** check box to print the module ID on reports.

For more information, see:
Data Monitor report (monitor format) on page E-79
Data Monitor report (report format) on page E-81

Start Cell No. Incremental If you select the **Start Cell No. Incremental** check box, the first test is performed in the cuvette that follows the one that was used for the final test of the previous run.

If you clear the check box, the first test is performed in the cuvette no. 1.

Reset Resets the first cuvette to be used in the following run to cuvette number 1.

Incubation Water Exchange Setting Select this check box to improve the Incubation Water Exchange function. If this function is activated, the incubator bath water is exchanged five times and approx. 8 ml EcoTergent is added during execution of the maintenance item **(5) Incubation Water Exchange**.

This function can be activated by an operator with administrator level only.

See *(5) Incubation Water Exchange* on page C-39.

Wash Rack Sampling See *Wash Rack Sampling* on page E-364.

3rd Results Acceptance

Select this check box to enable the **3rd Results Acceptance**. When **3rd Results Acceptance** is enabled, it is possible to request a test more than twice after acknowledging a safety warning. The rerun (second) result will be overwritten with the third result. The third result can be overwritten with a number of additional results. This function can be activated only if the system is connected to a host.

The repeated rerun is only performed if the previous rerun result has been sent to the host. If the previous result has not been transmitted prior to the repetition request, the sample is not pipetted.

Preconditions to activate 3rd. Results Acceptance

- Host communication has to be enabled on the **Start Conditions** screen.
- All previous results have to be sent to the Host and deleted on the analyzer.
- **Manual Rerun TS** has to be activated under **Utility** > **System (Page 1/4)** > **Host Comm.** > **Text Setting**.

Wash Rack Sampling

At the end of analysis each day, the inner wall of the sample probe, the ISE sample flow path and the IS bath are cleaned by processing a green wash rack.

Photometric

Use this text box to specify the number of cycles (5 to 30) for washing the sample probe and the waste flow path of the sample probe rinse station during the processing of the green wash rack. Recommendation: Do not change this setting. It should always be 5 cycles.

ISE

Use this text box to specify the number of cycles (5 to 30) for washing the ISE sample flow path during processing the green wash rack. Recommendation: Do not change this setting. It should always be 15 cycles.

For more information on processing a green wash rack, see *Processing green wash rack* on page C-69.

Buttons

Page X/4

The pages of buttons can be displayed alternately by choosing the **Page X/4** button. The Page button is labeled **Page 1/4** if you are viewing page 1, **Page 2/4** if you are viewing page 2, **Page 3/4** if you are viewing page 3 and **Page 4/4** if you are viewing page 4.

Alarm (Page 1/4)

Choose this button to activate some alarms.

See *Alarm Setting window* on page E-374.

Host Comm. (Page 1/4)

Choose this button to define the Host computer interface parameters.

See *Host Communication Setting window* on page E-376.

Comment (Page 1/4)

Choose this button to define the titles for the 5 demographic comments. These comments appear, for example, on the **Demographics** windows on the **Test Selection** and **Data Review** screens. The main comment can also be defined here.

See *Comment Title window* on page E-383.

Key Setting (Page 1/4) Choose this button to assign up to 5 groups of 32 keys for tests and profiles to the various sample types.

See *Key Setting window* on page E-384.

QC Setting (Page 1/4) Choose this button to display the **QC Setting** window and to define the type of QC accumulation.

See *QC Setting window* on page E-387.

Reagent Level (Page 2/4) Choose this button to define the regent level at which a yellow or purple alarm is issued.

See *Reagent Level Check window* on page E-388.

Calib Mask Setting (Page 2/4) Choose this button to display the **Calibration Mask Setting** window used to enable or disable automatic masking.

See *Calibration Mask Setting window* on page E-392.

Maintenance Setting (Page 2/4) Choose this button to define maintenance types and delete or edit existing ones.

See *Maintenance Setting window* on page E-393.

Pipe Setting (Page 2/4) Choose this button to create a new maintenance pipe, or to edit or delete an existing one.

See *Maintenance Pipe Setting window* on page E-397.

PowerUp Pipe Setting (Page 2/4) Choose this button to define which maintenance pipes are to be performed at power on.

See *Power Up Pipe Setting window* on page E-400.

Operator ID Setting (Page 3/4) Choose this button to define IDs and security levels for users or to activate or deactivate the password protection mode.

See *Operator ID Setting window* on page E-402.

If the system is not operating in password protection mode, you do not have to enter a password to access the software.

Check Digit Setting (Page 3/4) (barcode mode) Choose this button to enable/disable barcode check digits and to specify the method of check digit.

See *Check Digit window (barcode mode)* on page E-410.

ISE Calib Setting (Page 3/4) This window is used to set which ISE calibration curve that is used for the different sample types. On **c** 501 two calibration curves can be generated and used separately.

See *ISE Calibration Setting window* on page E-411.

Rack Delivery (Page 3/4) Use this window to make the following settings:

Photometric Stop Washing, activate or cancel **Rack Reception Mode** and set the corresponding time period. Set the number of rack rotor positions that are reserved for automatic QC and STAT racks and to activate or deactivate the function **Green Rack during Operation**.

For more information, see:
Rack Delivery window on page E-412
Green Rack during Operation on page E-413

Dil. + Cln. (Page 3/4) Use this window to confirm and update the registration status of dilution/cleaner cassettes (**c** 501 only).

See *Dilution and Cleaner Cassette Setting window (c 501)* on page E-415.

Auto. Print (Page 4/4) Choose this button to enable or disable automatic printout of the calibration monitor report, quality control results, and the emergency (STAT) sample results.

See *Automatic Printout Setting window* on page E-418.

Review By Exception (Page 4/4) Choose this button to define which data alarms, if present, prevent test results from being sent to the Host computer automatically. The upload has to be done manually if one of these data alarms occurs along with a test result.

See *Review By Exception window* on page E-419.

Rack Assignment window

➔ **Utility** > **System** > **Change** (**Rack Assignment** area)

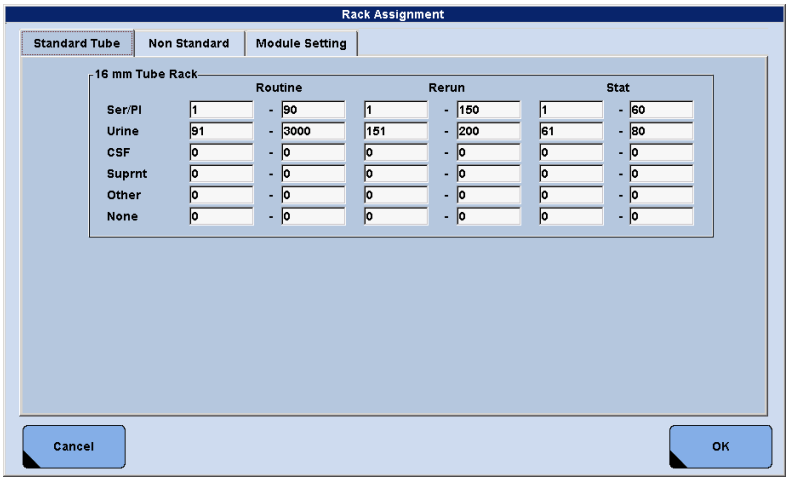


Figure E-213 Rack Assignment window - Standard Tube tab

This window consists of 3 tabs, which are displayed by choosing the respective tab titles: **Standard Tube**, **Non Standard**, and **Module Setting**. The **Standard Tube** and **Non Standard** tabs are used to assign rack ranges and tube types for routine, rerun, STAT and control samples and for each sample type (**Ser/Pl**, **Urine**, **CSF**…). The **Module Setting** tab is used for an optional assignment of calibrator racks and control racks to a specific **e** 601 module.

If there are still results on the **Data Review** screen, you are prompted to perform a **Sample Data Clear** prior to making changes.

Standard Tube tab

➔ **Utility** > **System** > **Change** (**Rack Assignment** area)

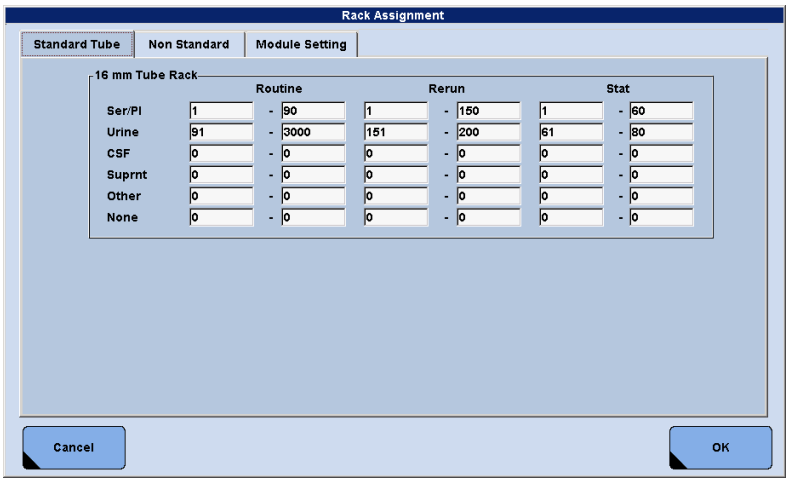


Figure E-214 Rack Assignment window - Standard Tube tab

16 mm Tube Rack area Use the **Standard Tube** tab to assign rack ranges for routine testing, rerun, and STAT measurements and for all sample types (**Ser/Pl**, **Urine**, **CSF**…) used.

Routine Use these text boxes to assign rack ranges to the available sample type for routine testing. The rack range can be entered in these two text fields (first rack no, last rack no).

Rerun Use these text boxes to assign rack ranges to the available sample type for rerun testing. The rack range can be entered in these two text fields (first rack no, last rack no).

Stat Use these text boxes to assign rack ranges to the available sample type for STAT testing. The rack range can be entered in these two text fields (first rack no, last rack no).

Non Standard tab

➔ **Utility** > **System** > **Change** (**Rack Assignment** area) >**Non Standard**

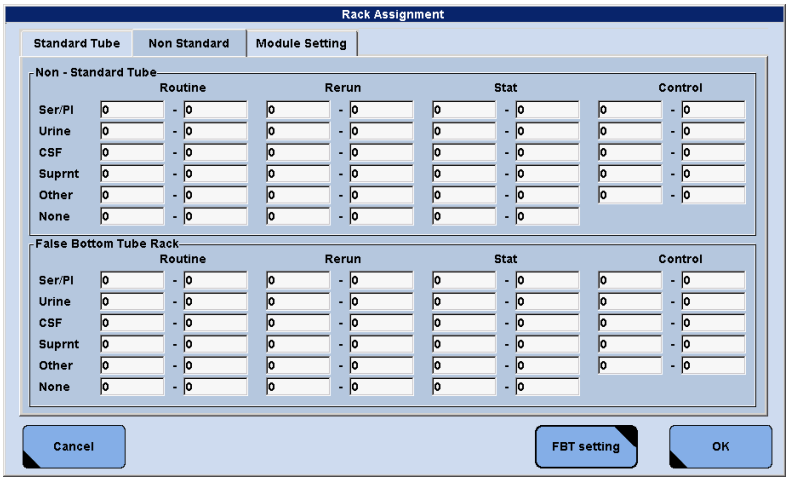


Figure E-215 Rack Assignment window - Non Standard tab

Use the **Non Standard** tab to assign rack ranges for non-standard tubes and false bottom tubes for routine testing, rerun, STAT and control measurements and the corresponding sample types (**Ser/Pl**, **Urine**, **CSF**…). Racks assigned on this tab must be used with non-standard tubes and false bottom tubes only.

Non standard tubes must have the following dimensions:

- Length between 73-102 mm (equivalent to 60 mm + Hitachi cup)
- Outer diameter between 12-16 mm

Please contact your Roche service representative for more information about the use of non-standard tubes and other sample containers.

Areas The **Non Standard** tab contains 2 areas:

- **Non-Standard Tube**
- **False Bottom Tube Rack**

Each area corresponds to one type of sample container. Non-Standard tubes and False Bottom tubes must have different rack ranges.

For more information, see:
Non-Standard Tube area on page E-370
False Bottom Tube Rack area on page E-370

FBT setting Choose this button to make settings for false-bottom/cup-on-non-standard tubes. These include settings for container height and bottom level.

See *False bottom/Cup on non-standard tube Setting window* on page E-372.

Non-Standard Tube area

Racks assigned in this area must be used with nonstandard sample tubes. It is possible to use different kinds of non-standard tubes and to mix these on a rack. However, it is not allowed to use cup-on-tube on the racks specified here.

Routine Use these text boxes to assign rack ranges to the available sample type for routine testing. **The racks within these ranges must be used with non-standard sample tubes.** The rack range can be entered in these two text fields (first rack no, last rack no).

Rerun Use these text boxes to assign rack ranges to the available sample type for rerun testing. **The racks within these ranges must be used with non-standard sample tubes.** The rack range can be entered in these two text fields (first rack no, last rack no).

Stat Use these text boxes to assign rack ranges to the available sample type for STAT testing. **The racks within these ranges must be used with non-standard sample tubes.** The rack range can be entered in these two text fields (first rack no, last rack no).

False Bottom Tube Rack area

Racks assigned in this area must be used only with false bottom tubes. The specification of this tube type must be given in the **False bottom/Cup on non-standard Tube Setting** window. To open this window choose the **FBT setting** button.

If you use cups on non-standard tubes, it is important to use only one type of non-standard tubes. The specification of these tubes must be given in the **False bottom/Cup on non-standard tube Setting** window. For the analyzer and the software configuration, there is no difference whether you use cups on non-standard tubes or false bottom tubes.

For further information, see *False bottom/Cup on non-standard tube Setting window* on page E-372.

Routine Use these text boxes to assign rack ranges to the available sample type for routine testing. The racks within these ranges must be used with the tube type configured in the **False bottom/Cup on non-standard tube Setting** window only**.** The rack range can be entered in these two text fields (first rack no, last rack no).

Rerun Use these text boxes to assign rack ranges to the available sample type for rerun testing. The racks within these ranges must be used with the tube type configured in the **False bottom/Cup on non-standard tube Setting** window only. The rack range can be entered in these two text fields (first rack no, last rack no).

Stat Use these text boxes to assign rack ranges to the available sample type for STAT testing. The racks within these ranges must be used with the tube type configured in the **False bottom/Cup on non-standard tube Setting** window only. The rack range can be entered in these two text fields (first rack no, last rack no).

Module Setting tab

➔ **Utility** > **System** > **Change** (**Rack Assignment** area) > **Module Setting**

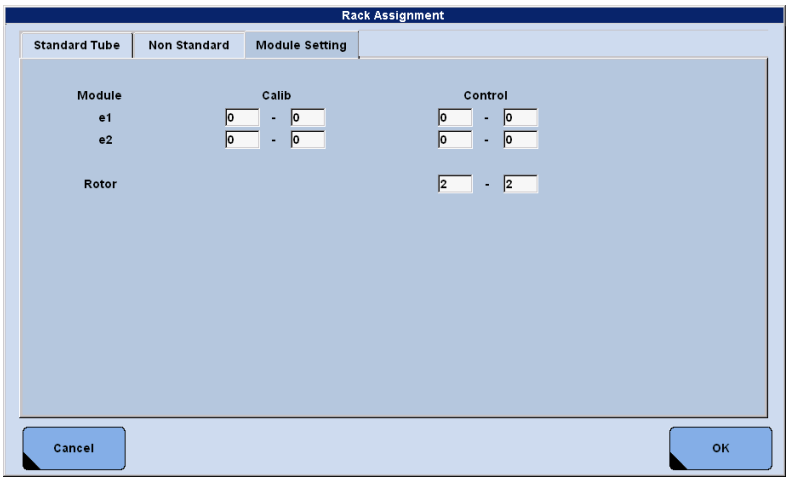


Figure E-216 Rack Assignment window - Module Setting tab

Use these text boxes to assign rack ranges for calibrators and controls to a specific **e** 601 module. These are optional fields to be used to force a calibrator or control rack to a certain module. These fields may be used to optimize calibrator and QC rack handling.

The racks which are defined for a specific **e** 601 module will not be processed on any other **e** 601 modules or **c** 501 modules of the system.

Module This column displays the name of each **e** 601 available on the system.

Calib. Use these text boxes to assign rack ranges for calibrator racks for a specific **e** 601 module. The rack range can be entered in these two text fields (first rack no, last rack no).

If 0 - 0 is entered in the **Calib** fields, then any calibrator rack number can be processed on any module.

Control Use these text boxes to assign rack ranges for control racks for a particular **e** 601. The rack range can be entered in these two text fields (first rack no, last rack no).

If 0 - 0 is entered in all **Control** fields, then any control rack number can be processed on any module.

Rotor Use these text boxes to assign a rack range for control racks that are to be used for auto QC measurements.

When loaded onto the analyzer, the assigned control racks remain in the rack rotor and get used whenever a QC measurement is requested and the auto QC rack contains the appropriate control material.

See *Automatic QC measurement* on page B-228.

False bottom/Cup on non-standard tube Setting window

➔ **Utility** > **System** > **Change** (**Rack Assignment** area) > **Non-Standard** > **FBT setting**

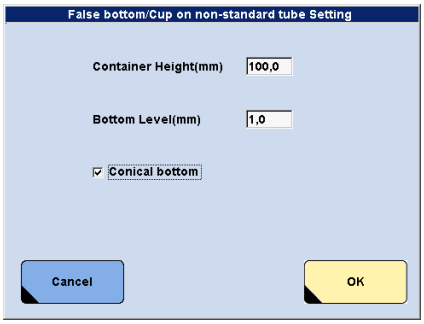


Figure E-217 False bottom/Cup on non-standard tube Setting window

Use this window to define the dimensions of the false bottom tubes/cup on non standard tube type that is used. The following measures must be defined:

Container height Length of the tube: 73-102 mm

Bottom Level When using false bottom tubes/cup on non standard tubes, the distance between the upper edge of the tube and the bottom level must be more than 20 mm.

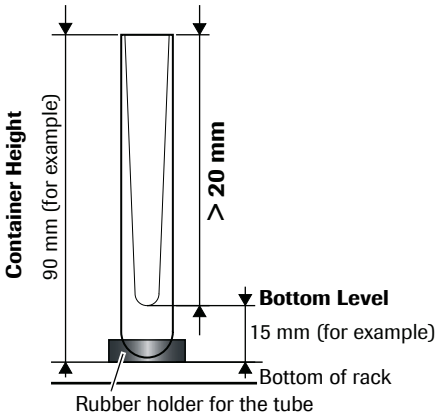


Figure E-218 False bottom tube settings

If you use tubes with conical bottom, select **Conical bottom**.

For exact specifications of the sample containers, contact the manufacturer.

The **Conical bottom** check box has only influence on the liquid level detection of the **e** 601 module. For systems with e 601 module it is recommended to activate the Conical bottom option.

Barcode Setting window

➔ **Utility** > **System** > **Change** (**Barcode Setting** area)

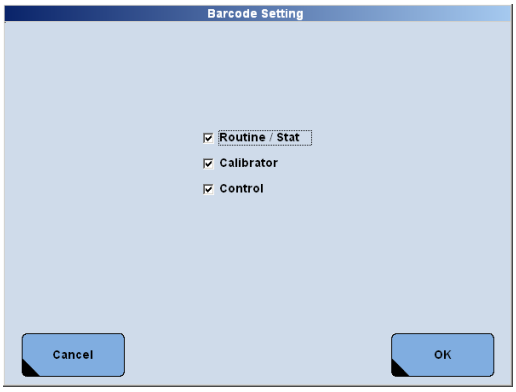


Figure E-219 Barcode Setting window

This window is used to toggle between barcode and non-barcode modes.

Routine/Stat Select this check box if you work with barcoded STAT and routine samples. If you work without barcodes you can enable the non-barcode mode by deselecting this check box.

Calibrator Select this check box if you work with barcoded calibrators. If you work without barcodes you can enable the non-barcode mode by deselecting this check box.

Control Select this check box if you work with barcoded controls. If you work without barcodes you can enable the non-barcode mode by deselecting this check box.

Alarm Setting window

➔ **Utility** > **System** (**Page 1/4**) > **Alarm**

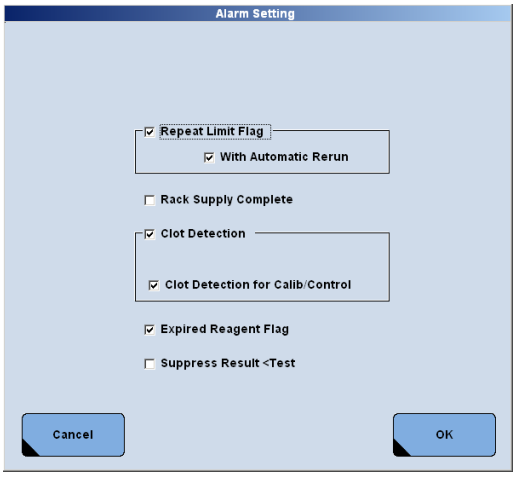


Figure E-220 Alarm Setting window

This window is used to activate user-definable alarm parameters.

Repeat Limit Flag Select this check box to enable, or deselect it to disable the repeat limit check. When this feature is enabled, the system utilizes the repeat limit flag according to the repeat limit values as defined on **Utility** > **Application** > **Range**. When this check box is selected, the **With Automatic Rerun** check box is also available.

For information on how to define the repeat limit, see *Range (c 501 ISE and photometric tests)* on page E-503.

With Automatic Rerun Select this check box to enable, or deselect it to disable the automatic rerun feature. When this feature is enabled, the system automatically reruns any result that is outside of the repeat limit range. The Automatic Rerun function is only activated if in addition, the rerun in global button **Start** > **Automatic Rerun** is activated. The repeat limit range is defined on **Utility** > **Application** > **Range**.

- This check box is not available if the **Repeat Limit Flag** check box is not selected.
- In case the result of an immunoassay is less than the lower limit value (below measuring range), an automatic rerun is not applied (**e** 601).

For further instructions, see:
To activate the automatic rerun function on page B-67
Range (c 501 ISE and photometric tests) on page E-503

Rack Supply Complete Select this check box to enable, or deselect it to disable the rack supply complete alarm. This alarm (caution level) is issued when there are no more racks available on the loader.

Clot Detection

Select this check box to enable, or deselect it to disable the clot detection feature for the sample probe on the **c** 501.

If a clot is detected, the sample probe is washed and the pressure is checked. If the pressure is OK, the analyzer continues with the next sample.

When this check box is selected, the **Clot detection for Calib/Control** check box is also available.

Clot Detection for Calib/Control

If the **Clot Detection for Calibrator/Control** check box is also selected, clot detection on the **c** 501 is also done when calibrators and controls are aspirated.

Expired Reagent Flag

Select this check box to enable, or deselect it to disable the expired reagent alarm. This alarm (caution level) is issued when a reagent is used beyond its expiration date. A data alarm ReagEx is attached to the test results on the **Workplace** > **Data Review** screen and to results on printouts as an indication for the operator that the results are not guaranteed. The expired reagents are listed on the reagent load/unload list with the alarm ReagEx.

Suppress Result < Test

Select this check box to enable, or deselect it to disable the suppress result for < *Test* function.

If this checkbox is selected and a measurement result is below the technical limit, the lower limit of the technical limit is displayed as the result flagged with a data alarm.



Lower technical limit for ISE tests required

If the *suppress result for < Test* function is enabled, lower technical limits for ISE tests are required. You must set the technical limit on the **Utility** > **Application** > **Range** screen manually.

For information on how to set the technical limit, see *Technical limit (c 501)* on page B-272.

If this checkbox is deselected and a measurement result is below the technical limit, the calculated result flagged with a data alarm is displayed.

Host Communication Setting window

➔ **Utility** > **System (Page 1/4)** > **Host Comm.**

This window is used to define the Host computer interface parameters. It is divided into 3 tabs: **Communication Setting**, **Text Setting** and **Result Upload Setting**.

👁 For details on the **Communication Setting**, **Text Setting** and **Result Upload Setting** tab, see:
Communication Setting on page E-376
Text Setting on page E-378
Result Upload Setting on page E-380

Communication Setting

➔ **Utility** > **System** (**Page 1/4**) > **Host Comm.** > **Communication Setting**

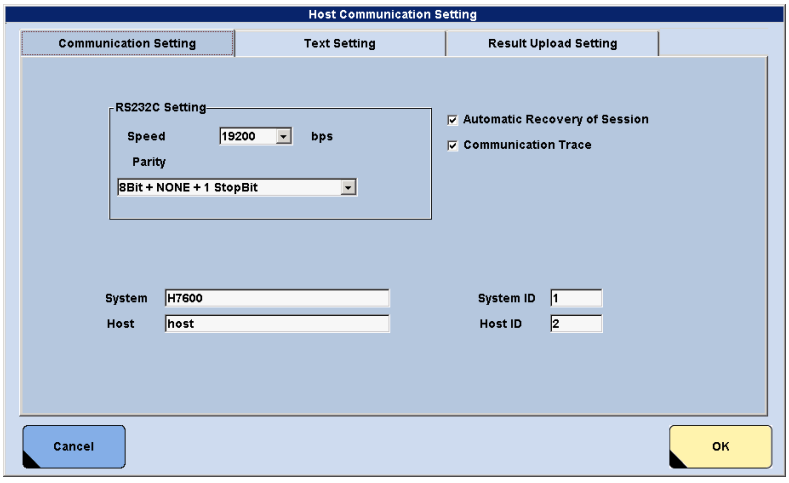


Figure E-221 Host Communication Setting window - Communication Setting tab

Use this tab to define the Host computer communication settings.

👁 For detailed information about Host communication settings, refer to the Host Interface Manual for the **cobas** 6000 analyzer series.

RS232C Setting area

Speed Use this list box to select the transmission speed in bps (bits per second) used for Host communication.

Parity Use this list box to select the number of data bits used for Host communication, parity code and the number of stop bits used for Host communication for the transfer of a data set.

For data bits, the choice is 7 or 8; for the parity code, the choice is **ODD**, **NONE** or **EVEN**. For Stop bits, the choice is 1 Bit or 2 Bits. The following combinations are available for selection from the list box:

7 BIT,	EVEN,	2 STOP BIT
7 BIT,	ODD,	2 STOP BIT
7 BIT,	EVEN,	1 STOP BIT
7 BIT,	ODD,	1 STOP BIT
8 BIT,	NONE,	2 STOP BIT
8 BIT,	NONE,	1 STOP BIT
8 BIT,	EVEN,	1 STOP BIT
8 BIT,	ODD,	1 STOP BIT

Automatic Recovery of Session Select this check box to specify automatic recovery of session data by the system in case of a transmission error.

Communication Trace Select this check box to specify recording the communication between the system and the Host. The recorded communication can be printed out, saved on FD, or deleted through **Print** (global button) > **Utility** > **Communication Trace** (list box). If this check box is clear, the communication trace is not recorded.

See *Communication Trace* on page E-154.

System Use this text box to define the analyzer name (up to 30 characters).

System ID Use this text box to define the analyzer's identification number (1 to 9). Each message that is sent from the Host uses this identification number.

Host Use this text box to define the Host name (up to 30 characters).

Host ID Use this text box to define the Host's identification number (1 to 9). Each message that is sent to the Host uses this identification number.

Text Setting

➔ **Utility** > **System** (**Page 1/4**) > **Host Comm.** > **Text Setting**



Figure E-222 Host Communication Setting window - Text Setting tab

Use this tab to define the text settings used for Host communications.

For detailed information about Host communication settings, refer to the Host Interface Manual for the **cobas** 6000 analyzer series.

Results Only Select the **Results Only** check box to send only results to the Host computer. If this check box is selected, the check boxes in the **Results Only** area are not available.

TS Timeout Select the check box to enable a test selection timeout. Enter the timeout interval (10 to 9999 seconds) in the adjacent text box. If the check box is deselected, no timeout is active, and the system waits indefinitely for test selections to be downloaded from the Host.

When the **TS Priority Mode** check box is selected, the TS timeout interval defaults to the maximum of 18 seconds.

Auto Rerun TS Select the check box to enable a test selection timeout for auto reruns.

If you need to enter a timeout interval, select the **Auto Rerun TS Timeout** check box and enter the timeout interval (10 to 9999 seconds) in the adjacent text box. If the **Auto Rerun TS Timeout** check box is deselected, no timeout is active, and the system waits indefinitely for test selections to be downloaded from the Host.

Manual Rerun TS Select this check box to specify rerun test selection inquiry to the Host when the system is in the manual rerun mode.

Stat TS Select this check box to specify STAT test selection inquiry.

TS Inquire Always Select this check box to enable, or deselect it to disable sending a test request to the Host system for each sample that is processed, even if a test selection has already been stored for the sample.

TS Ask in Barcode Read Error (barcode mode) Select this check box to specify that the system asks the Host for test selections using the rack ID and position number when a sample barcode is unreadable.

TS Priority Mode Select this check box to give precedence to test selection priorities downloaded from the Host over manual test selections.



- Selection of TS Priority Mode is possible only, when TS Timeout and Auto rerun TS Timeout are set between 10 and 18 seconds. Entries less than 10 and greater than 18 cause an error message (Entry out of range) when TS Priority Mode is selected.
- When the **TS Priority Mode** check box is selected, the TS Timeout and Auto Rerun Timeout intervals default to the maximum of 18 seconds.

Sample ID 22 Digits Select this check box to increase the maximum length of the sample ID from 13 to 22 characters.

Change Rack No. Select this check box to change the Rack ID before it is sent to the Host.

New Mode Select this check box to use the new mode protocol for Host communication.

Send 1st/Rerun Information Select this check box to add information that shows whether a query is first or rerun measurement to the request information record.

Send Comment Select this check box to specify inclusion of demographic information with test selection download and result transmission.

Send Conc. of Chemistry Qualitative Test Select this check box to send the concentration of the chemistry qualitative tests to the Host.

Send Time stamp of pipetting Sample Select this check box to send pipetting date and time (Time displayed in **Test Review** screen) for each test result to the Host.

Result Message Only for Immunoassay Qualitative Test Select this check box to send only the message value *reactive* or *non reactive* for qualitative **e** 601 test to the Host. If this check box is deselected, additionally the cutoff value is sent to the Host.

Chemistry Test Calibration Results Detail Select this check box to send additional details corresponding to the calibration result to the Host. The following additional information is sent to the Host:

- Reagent lot number
- **cobas c** pack sequence number
- Expired flag for reagent
- Calibrator lot number
- Calibration result time

Control Results Mode Incremental Select this check box to send control results test oriented. As soon as one test result of a control is available it is sent to the Host.

QC Additional Information Select the additional QC information that shall be sent to the Host. The following additional information is available:

- Control name
- Control Lot number

*Send Message for Quantitative Test (only for **e** 601 module)*

By activation of this function a defined result message (reactive, borderline, or non reactive) will be sent to Host.

This setting concerns a quantitative test which has a concentration value as a rule. As alternative a result message can be defined in **Utility** > **Application** > **Range** > **Expected Values**.

Result Message Border Range is used for *AHBSqual* (**e** 601) for US market only.

Button

Test Code to Host

Choose this button to edit the test code sent to the Host.

See *Host Test Code Setting window* on page E-382.

Result Upload Setting

➔ **Utility** > **System** (**Page 1/4**) > **Host Comm.** > **Result Upload Setting**

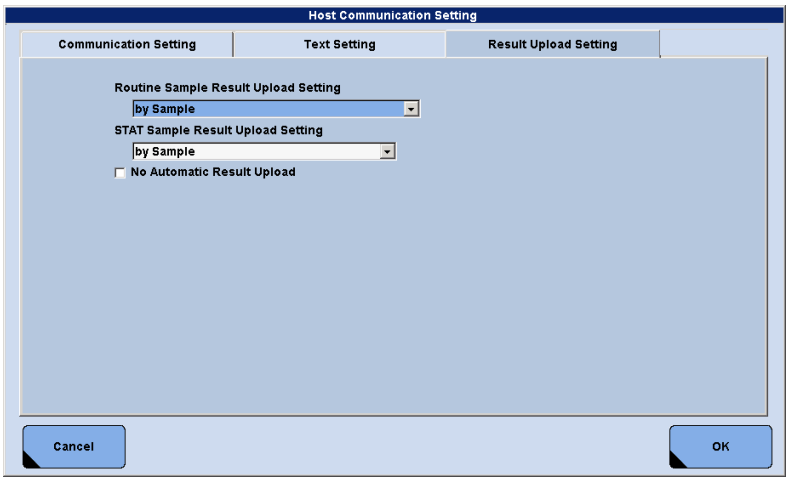


Figure E-223 Host Communication Setting window - Result Upload Setting tab

Use this tab to define the result upload settings used for Host communication.

For detailed information about Host communication settings, refer to the Host Interface Manual for the **cobas** 6000 analyzer series.

Routine Sample Result Upload Setting

With this function it is possible to select how the routine sample results are uploaded to the Host in real time. The following options are available:

- **by Sample**
- **Chemistry incl. ISE / Immunoassay**
- **ISE / Chemistry / Immunoassay**

For an explanation of each option, see *No Automatic Result Upload* on page E-381.

STAT Sample Result Upload Setting

Use this tab to define the upload settings used for the transfer of result data from the analyzer to the Host.

With this function it is possible to select how the STAT sample results are uploaded to the Host in real time. The following options are available:

- **by Sample**
- **by Test**
- **ISE / Chemistry / Immunoassay**
- **Chemistry incl. ISE / Immunoassay**

For an explanation of each option, see *No Automatic Result Upload* on page E-381.

No Automatic Result Upload

When this function is enabled, no result is uploaded in real time. In this case, the results can be uploaded manually by selecting samples from the **Workplace** > **Data Review** screen and choosing **Send To Host**.

by Sample	As soon as all results of a sample are available
by Test	Each time a test result is available
Chemistry incl. ISE / Immunoassay	As soon as all ISE and photometric results are available
	As soon as all immunological results are available
ISE / Chemistry / Immunoassay	As soon as all ISE results are available
	As soon as all photometric results are available
	As soon as all immunological results are available

Host Test Code Setting window

➔ **Utility** > **System** (**Page 1/4**) > **Host Comm.** > **Text Setting** > **Test Code to Host**

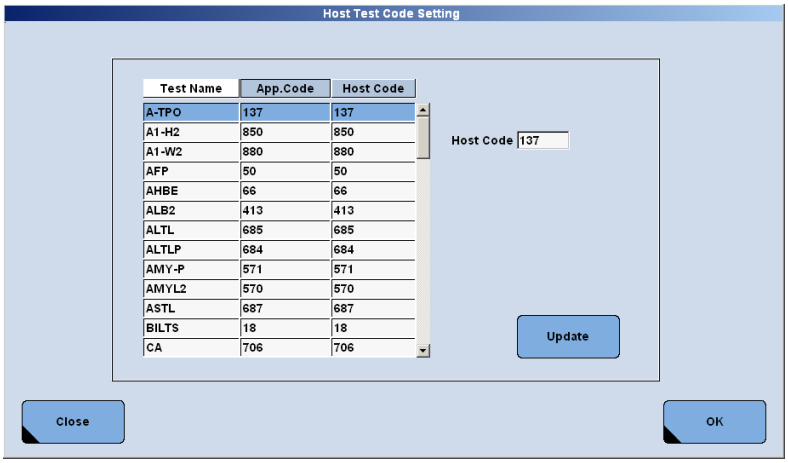


Figure E-224 Host Test Code Setting window

Use this window to edit the test codes which the system uses when communicating with the Host computer.

Test list

This list displays all tests, their application code and corresponding Host code that are available on the system. This list can be sorted by test (by choosing the **Test Name** tab) or **Host Code** (by to choosing the **Host Code** tab). The selected tab is highlighted in white.

Test Name The **Test Name** column displays the short test name of all tests available on the system.

App.Code The **App.Code** column displays the test application code used by the system to identify the test.

Host Code The **Host Code** column displays the Host Code used by the Host to identify the test.

Other elements

Host Code Use this text box to edit the Host code for the test selected in the test list.

Update Choose this button to transfer any changes to the list. After the **Update** button you have to select the **Save** button to save the changes.

Comment Title window

➔ **Utility** > **System** (**Page 1/4**) > **Comment**

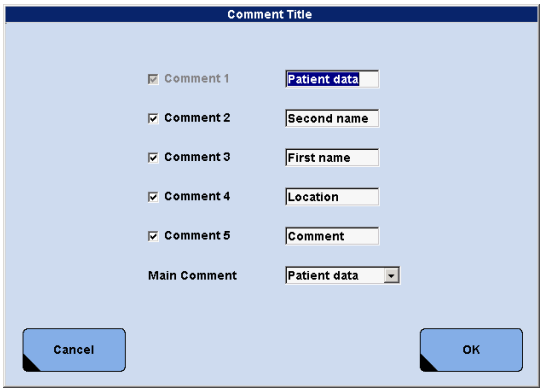


Figure E-225 Comment Title window

This window is used to define the titles for the 5 demographic comments and to enable or disable them. These comments appear, for example, on the **Demographics** windows of the **Test Selection** and **Data Review** screens.

Comment (1) … Comment (5) Select the check boxes to enable, or deselect them to disable the display of comments on the screens and on the patient report printouts. Use the text boxes displayed to the right of each comment field to define the name for each of the 5 comment lines (up to 12 characters) that appear throughout the software.

Main Comment Use this list box to select one of the comments defined above as the main comment. The main comment is displayed as a column title in lists, for example, **Workplace** > **Data Review**, and can be used as a search criterion in the **Sample Tracking** window.

Key Setting window

➔ **Utility** > **System (Page 1/4)** > **Key Setting**

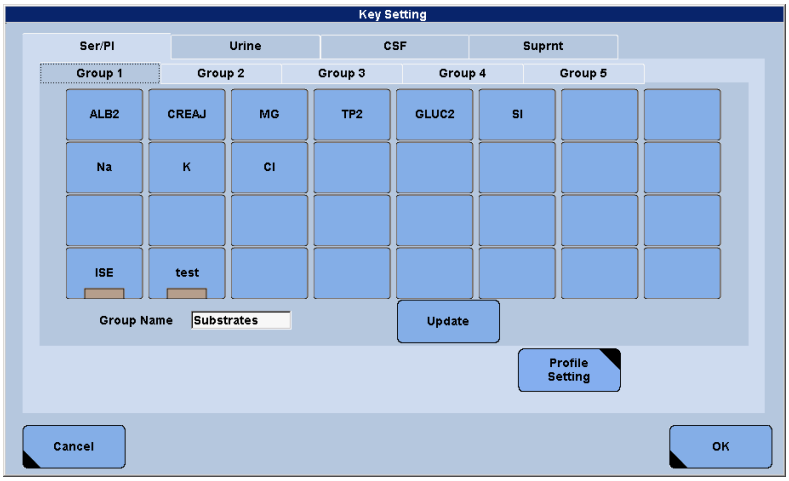


Figure E-226 Key Setting window

This window is used to assign tests or profiles to test keys. Only 1 test or profile can be assigned to each test key. Tests can be assigned for up to 5 groups of 32 keys per sample type.

Sample Type Tabs Use the 4 sample type tabs (**Ser/Pl**, **Urine**, **CSF** and **Suprnt**) across the top of the window to select the sample material to which the tests or profiles are to be assigned to.

Group Tabs 5 group tabs (Group 1 … Group 5) appear just below the sample and are used to select the group to which tests or profiles are assigned.

Test Keys Choosing a test key in the group number and sample type displays the **Key Setting** window. It is used to assign tests and profiles to the selected key. If a test has been assigned to a test key, the name is displayed on the key. If a profile has been assigned, the name of the profile and a brown bar are displayed on the key.

Group Name Use this text box to define the name of the selected group (up to 12 characters).

Buttons

Update Choose this button to transfer the changes to the data base. The button appears yellow when changes have been made. After the **Update** button the **OK** button has to be pressed to store the changes.

Profile Setting Choose this button to display the **Profile Setting** window used to define or edit a profile.

👁 See *Profile Setting window* on page E-386.

Key Setting window

➔ **Utility** > **System** (**Page 1/4**) > **Key Setting** > any test key

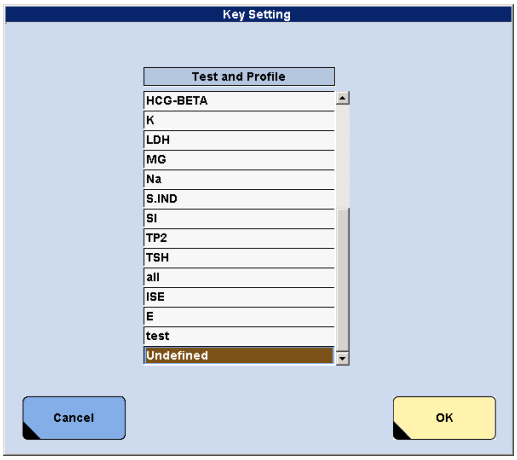


Figure E-227 Key Setting window

This window is used to assign a test or profile to the selected test key.

Test and Profile This list contains all tests and profiles valid for the selected sample type (**Key Setting** window) and is used to assign 1 test or profile to the selected test key.

To clear an existing assignment for a test key, select **Undefined** at the bottom of the list.

Profile Setting window

➔ **Utility** > **System** (**Page 1/4**) > **Key Setting** > **Profile Setting**

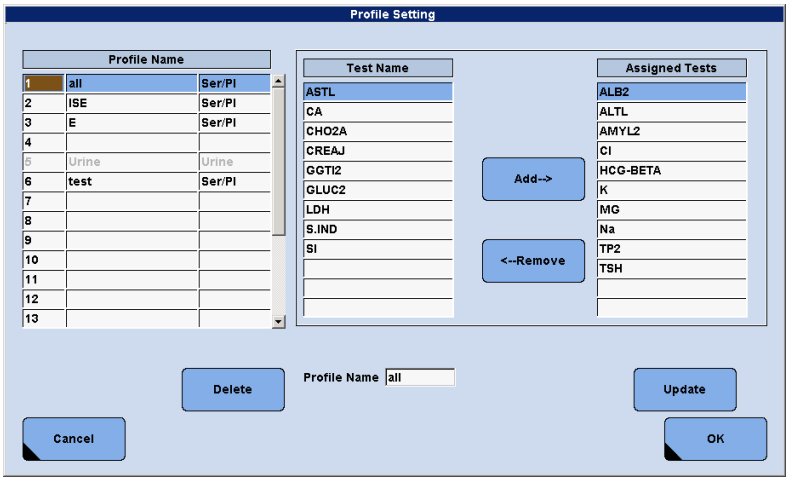


Figure E-228 Profile Setting window

This window is used to assign tests to a profile, or to edit or delete an existing profile.

Profile Name This list contains 20 positions available for profile name programming and displays defined profiles along with the sample type. It is used to select a profile position to be edited or added.

See *Default Profile Per Sample Type window* on page E-198.

Test Name This list displays the names of all tests available on the system. It is used to select tests to be added to the profile selected in the **Profile Name** list.

Assigned Tests This list displays the names of all tests assigned to the profile selected in the **Profile Name** list. It is used to view or remove tests of the profile.

Profile Name Use this text box to define a name for the selected profile (up to 8 characters).

Buttons

Add--> Choose this button to add the tests selected in the **Test Name** list to the profile selected in the **Profile Name** list. The tests are moved from the **Test Name** list to the **Assigned Tests** list.

<--Remove Choose this button to remove the tests selected in the **Assigned Tests** list and the profile. The tests are moved from the **Assigned Tests** list to the **Test Name** list.

Delete Choose this button to remove the selected profile from the **Profile Name** list after confirmation.

Update Choose this button to transfer any changes to the **Profile Setting** window. This button appears yellow when changes were made. To save the changes choose the **OK** button.

QC Setting window

➔ **Utility** > **System** (**Page 1/4**) > **QC Setting**

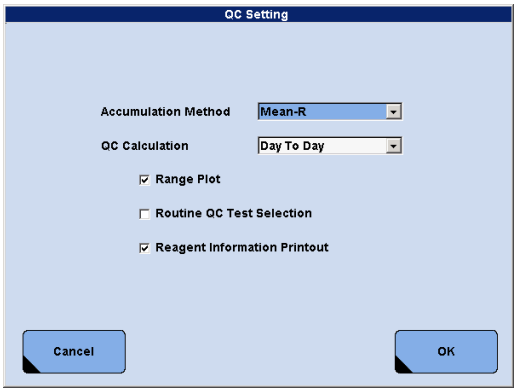


Figure E-229 QC Setting window

This window is used to define the type of QC accumulation. Accumulation can be performed by accumulating the individual QC result (Mean-R) or by accumulating one specific point (X-R).

Accumulation Method Use this list box to select the type of accumulation (**Mean-R** or **X-R**) used by the system. Selecting **Mean-R** transfers a mean value, either a weighted mean, according to the number of days used to calculate the mean, or a non-weighted mean. Selecting **X-R** transfers only 1 point. When **X-R** is selected, the point (1 to 2500) to be accumulated must be defined on **QC** > **Individual** > **Accumulate Data**.

QC Calculation Use this list box to select the method (**Day to Day** or **Overall**) the system uses for calculating the standard deviation for each accumulated control result. Selecting **Overall** calculates the SD with all weighted results. Selecting **Day to Day** calculates the SD with all equal results.

The **QC Calculation** list box is only available when **Mean-R** is selected in the **Accumulation Method** list box.

Range Plot Select this check box to enable, or deselect it to disable the range plot on the **QC** > **Cumulative** > **Cumulative QC Chart**. When the check box is selected, the range plot on the **Cumulative QC Chart** window shows the range between the accumulated data points.

See *Cumulative QC Chart window* on page E-336.

Routine QC Test Selection Select this check box to enable, or deselect it to disable the **Routine QC** test selection. This function defines whether or not the **Routine QC** test selections are used if the corresponding control is registered by the system /barcode reader and no other test selections are made on **QC** > **Status**.

Reagent Information Printout Select this check box to get additional reagent information on the QC data monitor printout. Lot number and sequence number (bottle/serial number) of the reagent are printed next to each result. Information concerning the status of the **cobas c** pack and **cobas e** pack or reagent pack (current/standby) is printed next to the test name.

Reagent Level Check window

➔ **Utility** > **System** (**Page 2/4**) > **Reagent Level**

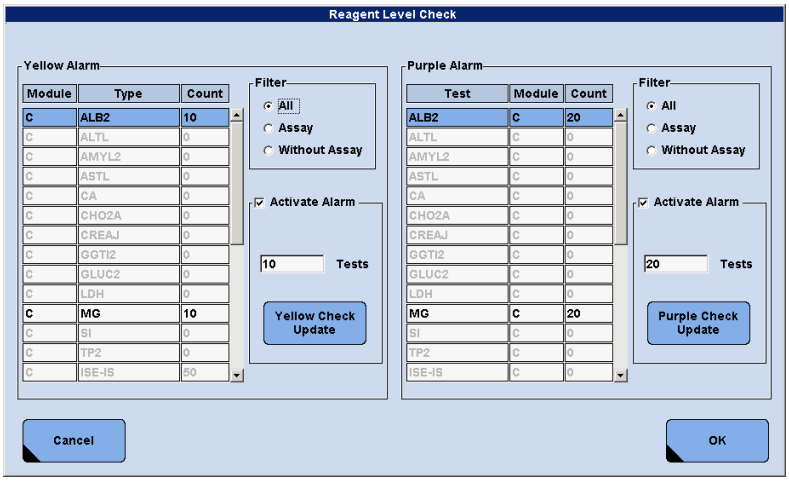


Figure E-230 Reagent Level Check window

This window is used to define the level of reagent at which a yellow or purple reagent level alarm is issued.

The system uses the following alarm levels to inform about the reagent level:

Purple	The purple alarm is intended to be used to set the amount of reagent for one day.
Yellow	The yellow alarm should be used to define a caution level for each reagent. When the yellow alarm is issued the required reagents should be provided.
Red	The red alarm indicates that the according reagent is empty. This is encoded in the software and cannot be changed.

The reagent level alarm is issued on the following screens, if the number of remaining tests / remaining volume is less than defined:

- On the **System Overview** screen the following buttons change their color to yellow or purple:
 - **Reagent Preparing** button
 - **Module** button
 - **Reagent Overview** button.
- On the **Reagent** > **Setting** screen the tests are marked in the corresponding color.
- On the **Reagent** > **Status** screen the tests are marked in the corresponding color if a single module is selected in the **Module** list box.

 If **All** is selected in the **Module** box, only red alarms are displayed, unless following cases:

 - The test is assigned to two modules and the corresponding **cobas e** packs are loaded on both modules. The according reagent on only one module is empty and on the other module it is not empty.
 - The required diluent for the test is empty or is not on board.

Yellow Alarm area

Use this area to define the number of determinations at which a yellow alarm is issued (reagent level alarm). This level can be set for individual tests, diluents and wash solutions. For wash solutions and diluents the reagent level has to be defined in ml.

Test list

Use the **Test** list to select a test, wash solution, or diluent of which the yellow alarm level is to be viewed or edited. The entries on the test list are grayed out if the **Activate Alarm** check box is not selected for a particular test.



The list does not only show the tests, diluents and wash solutions that are on board. It also shows the tests, diluents and wash solutions that are registered but currently not on board.

Module The **Module** column displays the name of the module on the system.

Type The **Type** column displays the test name.

Dil	Diluent (**cobas c** pack or **cobas e** pack)
Wash (D1)	NaOH-D c pack ACN 947 Cuvette wash solution, and solution for special wash programming
Wash (D2)	SMS c pack ACN 948 Solution for special wash program (reagent probe and cuvettes)
Wash (D3)	SCCS c pack ACN 949 Solution for special wash program (reagent probe and cuvettes)
BathDet	Detergent (EcoTergent) for incubation water bath
Wash (SP1)	Sample Cleaner 1 Sample probe wash solution for special wash program
Wash (SP2)	Sample Cleaner 2 Sample probe wash solution for special wash program
Wash (Cell1)	CellCln 1 / NaOH-D, for rinsing and cleaning cuvettes
Wash (Cell2)	CellCln 2 / Acid wash, for rinsing and cleaning cuvettes

Count The **Count** column displays the alarm level (in determinations or ml) currently defined.

Filter area

Use this area to filter the reagents displayed in the **Yellow Alarm** area by selecting the corresponding option **All**, **Assay** or **Without Assay**.

- **All** displays both, assay reagents and diluents/wash solutions.
- **Assay** displays the assay reagents registered on the system.
- **Without Assay** displays diluents and wash solutions.

Activate Alarm

Select the check box to activate the reagent level alarm for the test or solution selected in the test list.

If you clear this check box, the reagent level alarm is inactivated and the selected line on the test list gets grayed out.

Tests / mL Use this text box to define the reagent level at which a yellow alarm is issued.

For tests the level is defined as number of remaining determinations (**Tests**). For diluents and wash solutions, the level is defined in milliliters (**mL**).

Yellow Check Update Choose this button to transfer the changes made for the yellow alarm to the list. This button appears yellow when changes have been made. To save these changes select the **OK** button.

Purple Alarm area

Use this area to define the number of determinations at which a purple alarm is issued (reagent level alarm). This level can be set for individual tests, diluents and wash solutions. For wash solutions and diluents the reagent level has to be defined in ml.



Select the **Preventive Action** check box on the **System Overview** screen to activate the purple alarm. Purple alarms are issued only, if this check box is selected.

Test list

Use the **Test** list to select a test, wash solution, or diluent of which the purple alarm level is to be viewed or edited. The entries on the test list are grayed out if the **Activate Alarm** check box is not selected for a particular test.



The list does not only show the tests, diluents and wash solutions that are on board. It also shows the tests, diluents and wash solutions that are registered but currently not on board.

Test The **Test** column displays the test name.

Dil	Diluent (**cobas c** pack or **cobas e** pack)
Wash (D1)	NaOH-D c pack ACN 947 Cuvette wash solution, and solution for special wash programming
Wash (D2)	SMS c pack ACN 948 Solution for special wash program (reagent probe and cuvettes)
Wash (D3)	SCCS c pack ACN 949 Solution for special wash program (reagent probe and cuvettes)
BathDet	Detergent (EcoTergent) for incubation water bath
Wash (SP1)	Sample Cleaner 1 Sample probe wash solution for special wash program
Wash (SP2)	Sample Cleaner 2 Sample probe wash solution for special wash program
Wash (Cell1)	CellCln 1 / NaOH-D, for rinsing and cleaning cuvettes
Wash (Cell2)	CellCln 2 / Acid wash, for rinsing and cleaning cuvettes

Module The **Module** column displays the name of the module on the system.

Count The **Count** column displays the alarm level (in determinations or ml) currently defined.

Filter area

Use this area to filter the reagents displayed in the **Purple Alarm** area by selecting the corresponding option **All**, **Assay** or **Without Assay**.

- **All** displays both, assay reagents and diluents/wash solutions.
- **Assay** displays the assay reagents registered on the system.
- **Without Assay** displays diluents and wash solutions.

Activate Alarm

Select this check box to activate the reagent level alarm for the test or solution currently selected in the test list.

If you clear this check box, the reagent level alarm is inactivated and the selected line on the test list is grayed out.

Tests / mL Use this text box to define the reagent level at which the purple alarm is issued.

For tests the level is defined as number of remaining determinations (**Tests**). For diluents and wash solutions, the level is defined in milliliters (**mL**).

Purple Check Update Choose this button to transfer the changes made for the purple alarm to the list. This button appears yellow when changes have been made. To save these changes select the **OK** button.



Select the **Preventive Action** check box on the **System Overview** screen to activate the purple alarm.

Calibration Mask Setting window

➔ **Utility** > **System** (**Page 2/4**) > **Calib Mask Setting**

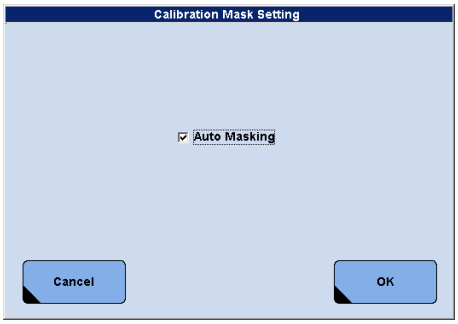


Figure E-231 Calibration Mask Setting window

This window is used to enable or disable automatic masking of tests due to a failed calibration.

Auto Masking Select this check box to enable, or deselect it to disable automatic masking of tests due to a calibration requirement. If it is activated sample requests for tests with a failed calibration will not be processed.

See *Calibration masking (auto masking)* on page B-239

Maintenance Setting window

➔ **Utility** > **System** (**Page 2/4**) > **Maintenance Setting**

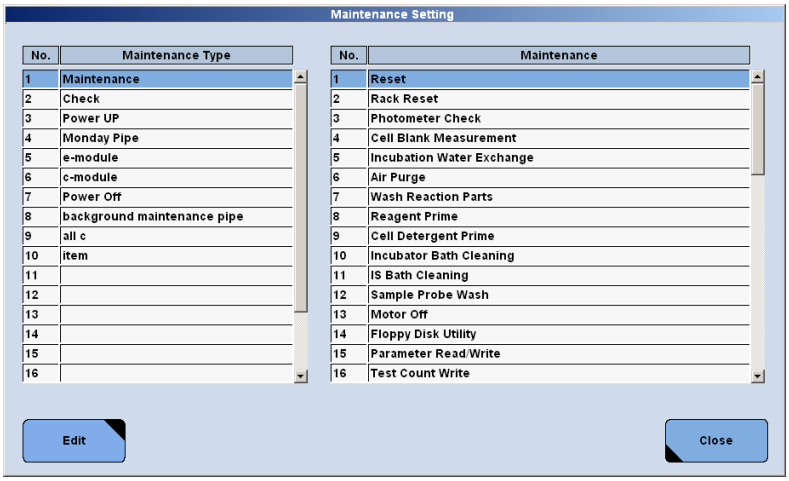


Figure E-232 Maintenance Setting window

Use this window to view and edit maintenance types.

For more information, see *Defining and editing maintenance types* on page C-19.

No. Maintenance Type This list displays up to 19 maintenance types. Select the type of maintenance to view.

No. Maintenance This list displays up to 40 maintenance items associated with the maintenance type selected in the **Maintenance Type** list.

For more information, see:
List of maintenance items on page C-38
List of maintenance checks on page C-43

Edit Choose this button to edit current maintenance types or define new maintenance types.

See *Edit Maintenance Type window* on page E-394.

Delete Choose this button to delete the maintenance type selected in the **Maintenance Type** list.

It is not possible to change the Maintenance Types (1) **Maintenance** and (2) **Check**. The **Edit** and **Delete** button is only displayed for maintenance types 3-19.

Edit Maintenance Type window

➔ **Utility** > **System** (**Page 2/4**) > **Maintenance Setting** > **Edit**

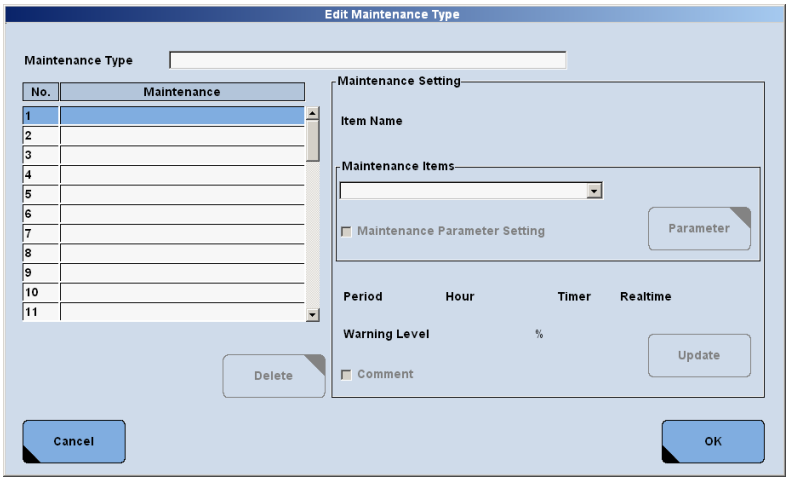


Figure E-233 Edit Maintenance Type window

This window is used to define new or edit maintenance types.

For more information, see *Defining and editing maintenance types* on page C-19.

Maintenance Type Type a name (up to 40 characters) to be displayed in the **Maintenance Type** list on the **Maintenance Setting** window.

No. Maintenance This list displays up to 40 maintenance items. Select a blank line in the list box to define a new maintenance item.

Item Name This text box displays the name of the currently selected **Maintenance** Item.

Maintenance Items Use this list box to select a maintenance item or pipe. Select **User Definable** to define a new maintenance item that is not automated by the system (i.e., clean instrument surfaces, check detergent level, etc.).

For more information, see:
Automating instrument care with maintenance pipes on page C-32
User Definable window on page E-396

Maintenance Parameter Setting Use this check box to enable the **Parameter** button, respectively to predefine parameter settings for maintenance items and checks. This check box is not available for maintenance pipes.

For more information, see *Parameter* on page E-395.

Period Type the maintenance interval (1 to 99) in this text box. Select the interval (Hours, Days, Months) from the list box. Enter 0 to cancel the warning level.

Timer Select the type of timer (Realtime, Power On, Operation) from this list box.

Warning Level Type the percent of time (1 to 99%) elapsed for the warning to be issued in this text box. Enter 0 to cancel the warning level.

Comment Select this check box to display the **Comment** field on the appropriate maintenance item window and to print the comment on the maintenance report.

Buttons

Delete Use this button to delete a selected maintenance item, check, or pipe.

Parameter Choose the **Parameter** button to predefine parameters for the selected maintenance item or check.

If you predefine the parameters of a maintenance item or check, the parameters are not definable during manual performing this maintenance item or check.

For more information, see *Performing maintenance items or pipes* on page C-13.

Update Choose this button to update the information.

User Definable window

➔ **Utility** > **System** (**Page 2/4**) > **Maintenance Setting** > **Edit** > **Maintenance Item: User Definable > Parameter** (**User Definable**)

Select **User Definable** from the **Maintenance** Items list box in the **Edit Maintenance Type** window.

Define a new maintenance item that is not automated by the system (i.e., clean instrument surfaces, check detergent level, etc.).

Choose **Parameter** to open the **User Definable** window.

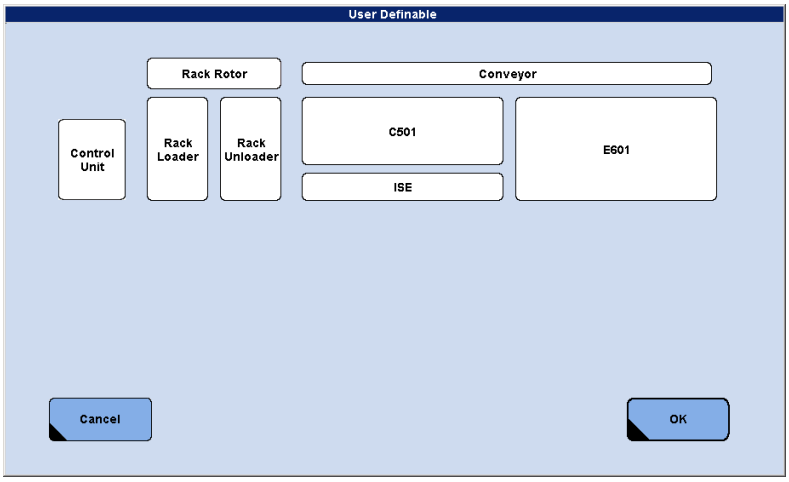


Figure E-234 User Definable window

Use this window to select the modules affected.

Maintenance Pipe Setting window

➔ **Utility** > **System** (**Page 2/4**) > **Pipe Setting**

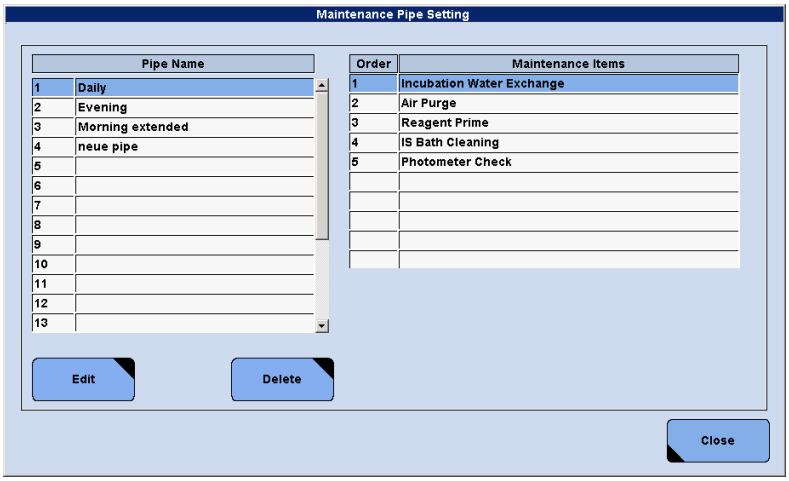


Figure E-235 Maintenance Pipe Setting window

Use this window is used to create a new maintenance pipe, or to edit or delete an existing one.

For more information, see *Defining and editing maintenance pipes* on page C-11.

Pipe Name This list displays 20 positions for maintenance pipe name programming. Maintenance pipe names already defined are displayed. Select a maintenance pipe to be edited or deleted or select a blank line to create a new pipe.

Order Maintenance Items This list displays the maintenance items already assigned to the maintenance pipe selected in the **Pipe Name** list. Up to 10 items can be assigned to a given pipe. The Order column lists the order in which the maintenance items will be performed.

Buttons

Edit Choose this button to create new maintenance pipes or make changes to existing ones.

For more information, see:
Defining and editing maintenance pipes on page C-11
Edit Pipe window on page E-398

Delete Use this button to delete the maintenance pipe selected from the **Pipe Name** list after confirmation.

Edit Pipe window

Utility > **System** (**Page 2/4**) > **Pipe Setting** > a line in **Pipe Name** list > **Edit**

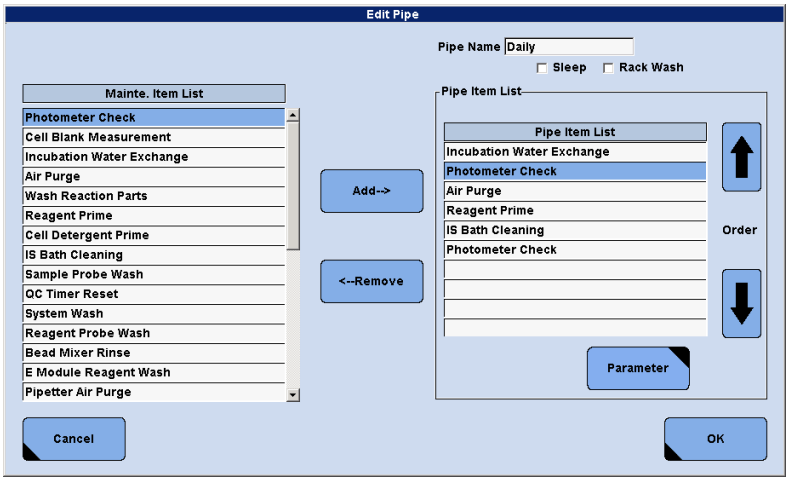


Figure E-236 Edit Pipe window

This window is used to create a new maintenance pipe or to edit existing ones.

Pipe Name Use this text box to enter a name (maximum of 15 characters) for the new pipe to be created. If you are editing an existing pipe, this text box displays the name of the pipe to be edited.

Sleep Select this check box to enable the sleep function. The sleep function enables the system to enter the sleep mode after the pipe function is completed. If the sleep function is disabled, the system will resume standby.

The sleep function will not be performed if the pipe is executed as a **Power Up Pipe** or **Start Up Pipe**.

Rack Wash Select this check box in order to carry out washing with a green wash rack before pipe operation. Thus, you can combine the processing of a green wash rack with the execution of a maintenance pipe for example, for pipes which are run at the end of a work shift. When the pipe is completed, the system turns to standby.

The green wash rack procedure will not be performed if the pipe is executed as a **Power Up Pipe** or a **Start Up Pipe**.

Mainte. Item List The **Mainte. Item List** displays all automated maintenance items available on the system. It is used to select maintenance items to be added to the current pipe.

Pipe Item List The **Pipe Item List** displays the maintenance items already assigned to the current pipe. It is used to select maintenance items to be removed from the pipe or to be re-ordered.

Buttons

Add--> Choose this button to add the maintenance item selected in the **Mainte. Item List** to the current pipe. The item is moved from the **Mainte. Item List** to the **Pipe Item List**.

<--Remove Choose this button to remove the maintenance item selected in the **Pipe Item List** from the current pipe. The item is moved from the **Pipe Item List** to the **Mainte. Item List**.

Order arrows Use these arrow buttons to move the maintenance item selected in the **Pipe Item List** to a new position in the list. Maintenance items are performed in the order they appear in the **Pipe Item List**.

Parameter Use this button to define parameters for the pipe item selected from the **Pipe Item List**. The parameter window displayed depends on the maintenance item selected. Use this parameter window to view the modules affected and, if applicable, set parameters such as prime cycles.

Power Up Pipe Setting window

➔ **Utility** > **System** (**Page 2/4**) > **Power Up Pipe Setting**

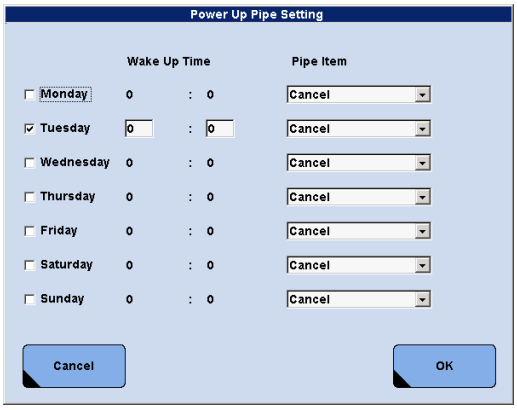


Figure E-237 Power Up Pipe Setting window

Use the **Power Up Pipe** function to select a pipe to be performed at power up of the system. In addition, you can set a wake up time when the power up of the system—and thus the selected pipe—is performed. However, the wake-up time takes effect only if the system was put in sleep mode before (and not put to shutdown status).

The following combinations are possible:

	Wake Up Time	Pipe Item	Action
☐ Monday	7:30	Power ON	The selected pipe (Power ON) is performed, when the system is powered on manually.
☑ Tuesday	7:30	Power ON	The system is woken up from sleep mode at 7:30. The selected pipe (Power ON) is performed.
☐ Wednesday	7:30	Cancel	No pipe is performed, when the system is powered on manually.
☑ Thursday	7:30	Cancel	The system is woken up from sleep mode at 7:30. No pipe is performed.

Table E-15 Power Up Pipe settings

For more information, see:
Maintenance pipes on page C-10
Defining and editing maintenance pipes on page C-11
Power Up Pipe function on page C-15
Automating instrument care with maintenance pipes on page C-32
Recommended maintenance pipes on page C-32
Maintenance Pipe Setting window on page E-397

Wake Up Time These fields display the wake up time of the system. The first text box displays the hours, the second the minutes. It is only possible to enter a wake up time, if the check box is activated.

Pipe Item This drop down list displays the pipes specified in the **Maintenance Pipe Setting** window. If **Cancel** is selected, no power up pipe will be executed upon wake up or power on.

The green rack wash procedure and the sleep function will not be performed during the Power Up Pipe, even though they are defined in the corresponding pipe settings.

Monday … Sunday Select the check box to enable the system to wake up at the specified time. If a power up pipe is selected, it will be executed after the system has waked up from sleep mode.

If the check box is not selected, the system is not waked up at the specified time. If a power up pipe is selected, it will be executed after powering on the system manually.

Operator ID Setting window

➔ **Utility** > **System** (**Page 3/4**) > **Operator ID Setting**

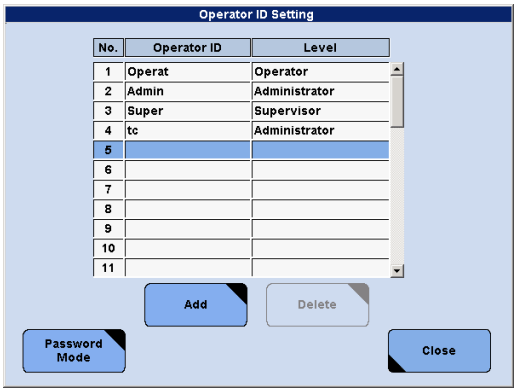


Figure E-238 Operator ID Setting window

This window is used to assign user IDs and access levels.

At least 1 administrator level logon ID must remain in the system at all times.

After an operator ID is established, the password entered in the first time the operator ID is used for logon becomes the permanent password for this operator ID.

If a password for an existing operator has been lost, the ID must be deleted and reentered.

No. Operator ID Level This list displays IDs with their security levels defined on the system. Possible levels are **Administrator**, **Supervisor** and **Operator**. These levels allow the user different access rights to screens, windows, fields and functions of the software. Up to 40 IDs can be defined.

Buttons

Add Use this button to display the **Add Operator ID** window. This window is used to add a new operator ID to the system.

See *Add Operator ID window* on page E-403.

Delete Use this button to delete the selected ID from the system after confirmation.

Add Operator ID window

➔ **Utility** > **System** (**Page 3/4**) > **Operator ID Setting** > **Add**

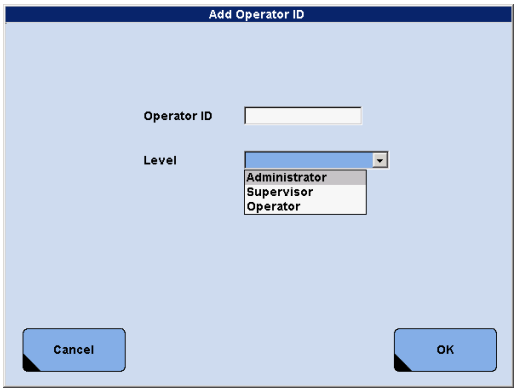


Figure E-239 Add Operator ID window

This window is used to add a new operator ID to the system. Up to 40 IDs can be assigned.

Operator ID Use this text box to enter an operator ID (up to 6 characters).

Level Use this list box to select the access level for the new operator ID. Possible levels are **Administrator**, **Supervisor** and **Operator** (in descending order of access rights).

When assigning operator IDs, it is important to provide the user with the correct access level for the tasks to be performed.

Operator	Access to routine operation without system setting
Supervisor	Basic system setting
Administrator	System configuration and maintenance setting

Overview of access levels

Access level	O: Operator	S: Supervisor	A: Administrator
Access rights	-: not available	R: Read only	E: Editable

Add Operator ID window

Main screens

This section shows the access levels of the main screens.

Workplace menu The following table shows the access levels of the **Workplace** menu.

Screen	Button	Purpose	O	S	A
Test Selection		Register sample test and check/change rerun item	E	E	E
	Demographics	Enter demographic data	E	E	E
	Barcode Read Error	Enter sample data in case of barcode read error	E	E	E
	Rerun Rack Assignment	Assign rerun rack No. and position (non-barcode mode)	E	E	E
	Repeat	Assign same request for multiple samples	E	E	E
	Previous	Jump to previous test selection	E	E	E
	Next	Jump to next test selection	E	E	E
	Save	Save sample test selection	E	E	E
Data Review		Check measurement result	E	E	E
	Demographics	Enter demographic data	E	E	E
	Filter (radio button)	Activate the filter	E	E	E
	Data	Select the database to be displayed	E	E	E
	Search	Search for the sample result	E	E	E
	Filter	Filter sample results	E	E	E
	Send to Host	Transmit results to Host system	E	E	E
	Delete Record	Delete individual results	E	E	E
	Delete All	Delete all results	E	E	E
	Backup Data	Save results to disk	-	E	E
	Test Review	Check and edit sample results	E	E	E
	Reaction Monitor	View photometric reaction curve	E	E	E
Calib. Review		Check currently processed calibrators	E	E	E
	Delete Calibrator	Delete selected calibrator	E	E	E
	Delete Test	Delete any test of a calibrator	E	E	E

Table E-16 Workplace menu - access levels

Reagent menu The following table shows the access levels of the **Reagent** menu.

Screen	Button	Purpose	O	S	A
Setting		Check reagent setting	E	E	E
	Manual Registration	Manual registration of reagent	E	E	E
	Cassette Unloading	Unload a cassette manually	E	E	E
	Open Channel	Assign a **cobas c** pack MULTI to a development channel application	E	E	E
	Delete	Delete reagent from list	E	E	E
	Reagent Prime	Reagent exchange	E	E	E
Status		Check reagent status	E	E	E
	Inventory Set	Enter ProCell lot No.	E	E	E
	Reagent Volume Reset	Reset the remaining volume of detergents for **c** 501	E	E	E

Table E-17 Reagent menu - access levels

Calibration menu The following table shows the access levels of the **Calibration** menu.

Screen	Button	Purpose	O	S	A
Status		Save, check and change test calibrations	E	E	E
	Start up	Check and save startup calibrations	E	E	E
	Start up Setting		R	E	E
	Reject	Reject calibration result	E	E	E
	Calib Trace	Trace of calibration result	E	E	E
	Calibration Result (Photometry)	Display a list of calibration results	R	E	E
	Working Information	Display the calibration curve	R	E	E
	Calibration Factor	Display the calibration factors	E	E	E
	Calibration Result (ISE)	Display the results from the most recent successful calibration	E	E	E
	Compensated Value	Display the difference between the target value and measured value	R	E	E
	Calibration Result (**e** 601)	Display the results from the most recent successful calibration	R	E	E
	Instrument Factor	Enter a coefficient for correction of differences between instruments	R	E	E
	Reaction Monitor	View photometric reaction curve	E	E	E
	Save	Save test calibration	E	E	E
Calibrator		Check and add rack to set calibrator	R	E	E
	Rack Assignment	Add and delete rack No. and position	-	E	E
Install	Photometry/ ISE	Addition and change of test for each calibrator	R	E	E
	Add	Add calibrator	-	E	E
	Delete	Delete calibrator	-	E	E
	Edit	Edit calibrator	-	E	E
	Download	Download calibrator data from **cobas** link	-	E	E
	Immune	Addition and change of test for each calibrator	R	E	E
	Download	Download calibrator information	-	E	E

Table E-18 Calibration menu - access levels

QC menu The following table shows the access levels of the **QC** menu.

Screen	Button	Purpose	O	S	A
Status		Save, check and change test quality control	E	E	E
	Routine QC	View Routine QC	E	E	E
	Routine QC Assign	Assign routine QC	E	E	E
	Stand By Bottle QC	Set QC for standby reagent pack	E	E	E
	Automatic QC Unloading	Unloads automatic QC racks	E	E	E
	Save	Save QC	E	E	E
Run Status		Overview of QC measurements	E	E	E
Individual		Check individual QC data	E	E	E
	Chart	Display individual QC chart	E	E	E
	Realtime QC	Display realtime QC chart, assign controls, and select rules	R	E	E
	Accumulate	Add individual QC data to cumulative data	E	E	E
	Delete	Partial rejection of individual QC data	-	E	E
Cumulative		Check of cumulative data	E	E	E
	Chart	Display cumulative QC chart	E	E	E
	Delete	Delete cumulative data	-	E	E
Control		Check and add rack to set control	R	E	E
	Rack Assignment	Add and delete rack No. and position	-	E	E
Install		Add and change test for QC sample	-	E	E
	Add	Add new QC sample manually	-	E	E
	Delete	Delete QC sample	-	E	E
	Download	Download new QC sample	-	E	E
	Edit	Save concentrations for test	-	E	E
	Activate / Inactivate Test	Select or deselect a test for QC sample	-	E	E

Table E-19 QC menu - access levels

Utility menu The following table shows the access levels of the **Utility** menu.

Screen	Button	Purpose	O	S	A
System		Configure instrument	-	-	E
	Change (Rack Assignment)	Change rack assignment	-	-	E
	Change (Barcode Setting)	Change barcode setting	-	-	E
	Reset (Start Cell No.Incremental)	Reset start cell number	-	-	E
	Incubation Water Exchange Setting	Enable the improved Incubation Water Exchange	-	-	E
	3rd Results Acceptance	Enable the 3rd Results Acceptance	-	-	E
(Page 1/4)	Alarm	Set alarm settings	-	-	E
	Clot Detection		-	-	R
	Calibrator/Control		-	-	E
	Repeat Limit Flag		-	-	E
	Rack Supply Complete		-	-	E
	Host Comm.	Configure Host communication parameters	-	-	E
	Comment	Define comment titles	-	-	E
	Key Setting	Set test groups and test key	-	-	E
	QC Setting	Set QC method	-	-	E
(Page 2/4)	Reagent Level Check	Set purple and yellow reagent check levels	-	-	E
	Calib Mask Setting	Set automatic masking	-	-	E
	Maintenance Setting	View maintenance item	-	-	E
	Edit Maintenance Type	Define maintenance item parameters	-	-	E
	Pipe Setting	Define maintenance pipes	-	-	E
	Power Up Pipe	Set maintenance pipe for power up	-	-	E
(Page 3/4)	Operator ID Setting	Assign operator IDs	-	-	E
	Check Digit	Set sample ID barcode check method	-	-	E
	ISE Calib Setting	Set an ISE calibration curve	-	-	E
	Rack Delivery Setting	Set Rack Reception mode, automatic QC and Green Rack during Operation	-	-	E
	Dil.+Cln.	Confirm the registration status of diluents and cleaners	-	-	E
(Page 4/4)	Automatic Printout	Set automatic printouts	-	-	E
	Review By Exception	Exclude selected data from being sent to host	-	-	E
Maintenance		Execute maintenance	E	E	E
	Monitor	Monitor current maintenance procedure	E	E	E
	Select	Specify module for maintenance	E	E	E
Application		Register application parameters	-	R	E
	Delete	Delete application	-	-	E
	Download	Download new applications	-	-	E
Calc. test		Program calculated and compensated tests	-	R	E
	Edit	Edit calculated and compensated tests	-	-	E
	Delete	Delete calculated and compensated tests	-	-	E

Table E-20 Utility menu - access levels (Sheet 1 of 2)

Add Operator ID window

Screen	Button	Purpose	O	S	A
Special Wash	Photometry	Define carryover prevention actions	-	R	E
	Edit	Edit Reagent Probe, Cell and Sample Probe carryover actions	-	-	E
	Delete	Delete Reagent Probe, Cell and Sample Probe carryover actions	-	-	E
	Immune	Define carryover prevention actions	-	R	E
	Edit	Edit Reagent Probe and Sample Probe carryover actions	-	-	E
	Delete	Delete Reagent Probe and Sample Probe carryover actions	-	-	E
Report Format		Set printout format	-	-	E
Module Set		Set module operating conditions	-	-	E
	Test Assignment	Assign parameters to modules	-	-	E
	Module Setting	Set module masking	-	-	E

Table E-20 Utility menu - access levels (Sheet 2 of 2)

Global screens

Screen	Button	Purpose	O	S	A
System Overview					
Work Flow Guide area	Daily Maintenance	Jump to Maintenance screen			
	Sample Data Clear	Delete all sample data	E	E	E
	Reagent Preparing	Print reagent load list and perform a reagent prime	E	E	E
	Calibration and QC Select	Request calibration and QC and print load lists	E	E	E
	Parameter Download	Download applications, calibrator or control parameters from **cobas** link	E	E	E
	Sample Tracking	Check sample status	E	E	E
Module Overview area	Module buttons	Indicate status of modules	E	E	E
Buttons area	Backup Operation	Start backup operation mode	E	E	E
	Alarm	Jump to Alarm screen	E	E	E
	Reagent Overview	Indicate status of reagents and inventory	E	E	E
	Cancel Maintenance	Cancel maintenance function	E	E	E
Stop		Specify operation stop	E	E	E
Shutdown		Shutdown the instrument, Log off, or enter Sleep mode	E	E	E
S. Stop		Specify sample stop	E	E	E
Alarm		Review alarm list and remedy	E	E	E
	Delete	Delete alarm	E	E	E
	New Alarm	Update alarm list	E	E	E
	Sound	Adjust buzzer sounds	E	E	E
	Maint.	Jump to Maintenance screen	E	E	E
Print		Print reports for each menu	E	E	E
	Work Place	Print routine measurement data	E	E	E
	Reagent	Print reagent data	E	E	E
	Calibration	Print calibration data	E	E	E
	QC	Print QC data	E	E	E
	Utility	Print utility data	E	E	E
	View	Display reports on screen	E	E	E
Start		Enter analysis start conditions	E	E	E
	Masking	Mask test per channel	E	E	E
	Default Profile	Define default profiles	-	-	E

Table E-21 Global screens and access levels

Check Digit window (barcode mode)

➔ **Utility** > **System** (**Page 3/4**) > **Check Digit Setting**

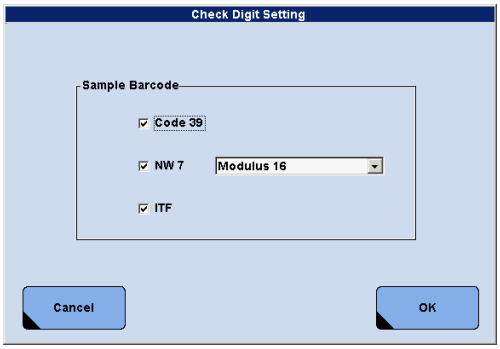


Figure E-240 Check Digit Setting window

This is used to enable or disable barcode check digits, which are used to verify the number of the sample tubes' barcode labels. Any combination of the 3 barcode checks can be selected.

Code 39 Select this check box to enable, or deselect it to disable check digits for Code 39 type barcodes.

NW 7 Select this check box to enable, or deselect it to disable check digits for NW 7 type barcodes. When the check box is selected, a list box appears to the right of the check box. Select the method of check digit from the list box. Options include: **Modulus 16**, **Modulus 11**, **Modulus 10/2 Weight**, **Modulus 10/3 Weight**, **7 Check DR**, **Weight Modulus 11** and **Modulus 10/2 Weight-A**.

ITF Select this check box to enable, or deselect it to disable check digits for ITF type barcodes.

ISE Calibration Setting window

➔ **Utility** > **System** (**Page 3/4**) > **ISE Calib Setting**

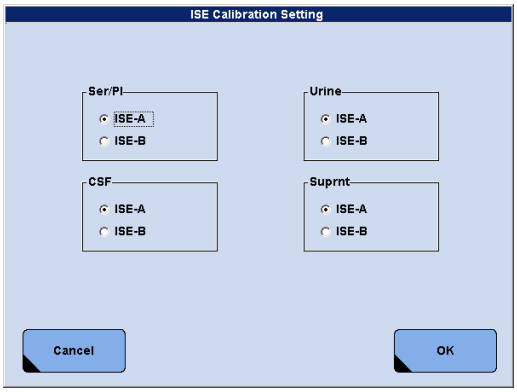


Figure E-241 ISE Calibration Setting window

Use the **ISE Calibration Setting** window to assign an ISE calibration curve to each sample type.

For more information, see:
Calibration concept - ISE applications on page B-159
Other (c 501 ISE tests) on page E-510

Ser/Pl Urine CSF Suprnt The areas display the different sample types.

ISE-A ISE-B This option buttons display the two different calibration curves for ISE.

Rack Delivery window

➔ **Utility** > **System** (**Page 3/4**) > **Rack Delivery**

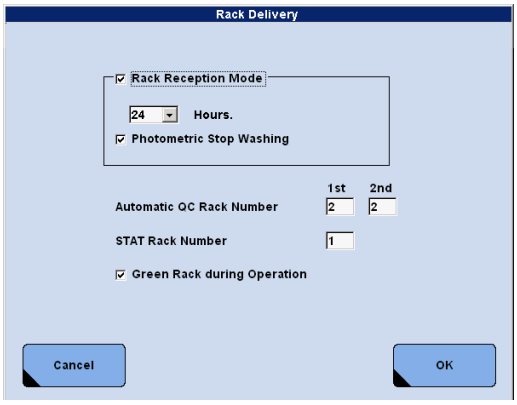


Figure E-242 Rack Delivery window

Use this window to make the following settings:

- Activate or cancel **Rack Reception Mode**, set the time period. The following periods are available: **1**, **2**, **4**, **8**, **12** and **24 hours**.
- Activate or cancel **Photometric Stop Washing**.
- Set the number of rack rotor positions that are reserved for automatic QC and STAT racks
- Activate or cancel **Green Rack during Operation**.

Automatic QC Rack Number / STAT Rack Number

Set the number of slots for each rotor that will be reserved for **Automatic QC** and STAT racks during operation.

The reserved number of slots will be used by the automatic QC or STAT racks. The number of slots reserved for automatic QC should correspond with the specified rack range for automatic QC racks.

The numbers of reserved slots for **Automatic QC** racks can be defined independently for each rotor. The reserved rack positions for STAT racks in the second rack rotor cannot be defined. On this rack rotor one rack position is reserved for STAT racks per default.

See *Automatic QC measurement* on page B-228.

At least one position should be reserved for a STAT rack!

If no position is reserved for a STAT rack and all positions are occupied by other racks, the STAT rack cannot be processed until a rack is removed from the rack rotor.

Recommendations for reserved STAT positions in rack rotor:

- With system automatic rerun activated up to a maximum of 5.
- Without system automatic rerun activated up to a maximum if 10.

Green Rack during Operation

Select this check box to activate the **Green Rack during Operation** function. When this function is activated, you can load a green wash rack during operation. The analyzer will not go into standby after processing of the green wash rack. Therefore a continuous processing of samples is possible.

See *Processing green wash rack* on page C-69.

Rack Reception Mode

Select this check box to activate and configure the rack reception mode (RRM). When the rack reception mode is activated, you can choose this mode on the **Start Conditions** screen.

See *Start Conditions screen* on page E-186.

For an analysis started without RRM, the system automatically goes into standby after the last available sample is processed.

For an analysis started with active RRM, the system remains in operation after the last available sample is processed and until one of the following occurs:

Action	Result
Specified time is elapsed	System goes into standby
S.Stop button is chosen	System goes into standby
Stop button is chosen	System goes into standby
A red alarm is issued	System goes into standby
A wash rack is loaded	The wash rack is processed and then the system goes into standby

Table E-22 Stopping the system in rack reception mode

If there are still samples to be processed after the RRM time has elapsed, the system finishes these samples and goes to standby afterwards.

The **Rack Reception Mode** area is displayed only if the **MPA Connection Mode** is disabled.

See *MPA Connection Mode window* on page E-194.

Interrupt RRM

If you want to stop the RRM before the specified time is elapsed, proceed as follows:

► To interrupt the Rack Reception mode

1. Choose **Start** (global button).
2. Choose **Change** in the **Rack Reception Mode** area.
3. Clear the R**ack Reception Mode** check box and confirm with **OK**.

 The Rack Reception Mode is stopped. The system goes into standby.
4. Choose **Cancel** to close the **Start Conditions** screen.

■

- The remaining time for RRM is shown in the status line.
- Changes to the duration of the rack reception mode can only be done in standby.
- The system goes into standby after 24 hours if 24 hours is specified as the duration of the rack reception mode.

Hours.

Use the **Hours** list box to specify the duration of the rack reception mode. The following periods are available: **1**, **2**, **4**, **8**, **12** and **24 hours**. The count down for the remaining time starts, when the system changes to operation mode. The remaining time for RRM is shown in the status line.

See *Start Conditions screen* on page E-186.

*Photometric Stop Washing (**c** 501)*

During operation and rack reception mode the reaction cells of the **c** 501 module are continuously washed. To disable the washing function, select the **Photometric Stop Washing** check box. In this case washing stops, after the last sample is processed.

Cell washing is automatically enabled when the next analysis is started.

This check box is available only if rack reception mode is selected.

Dilution and Cleaner Cassette Setting window (c 501)

➔ **Utility** >**System** (**Page 3/4**) > **Dil. + Cln.**

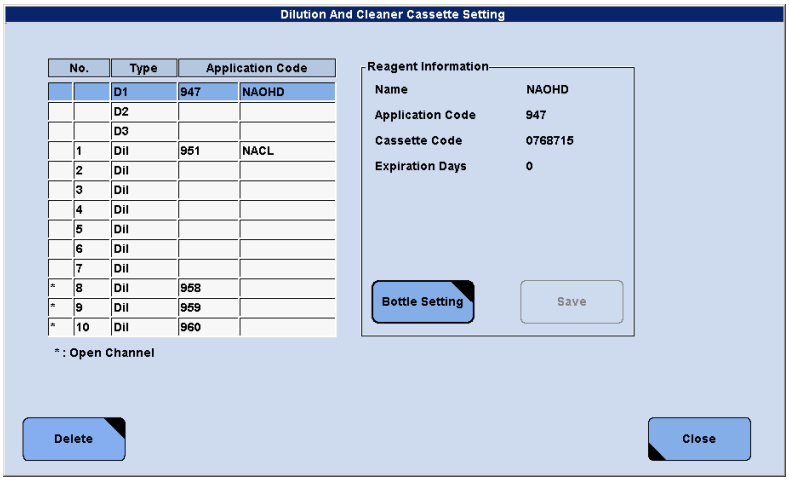


Figure E-243 Dilution and Cleaner Cassette Setting window

Use this window to confirm and update the registration status of diluent/cleaner cassettes.

Before a diluent/cleaner can be used on the **c** 501, you have to download the information from **cobas** link.

Table List

No. The **No.** column displays a blank for detergent types **D1**, **D2** or **D3**. The diluents are numbered from 1 to 10.

Type The **Type** column displays the reagent type **D1**, **D2** or **D3** for detergent 1 to 3 or DIL for diluents. The numbers 8 to 10 are development channel (open channel) items and displayed as * + number.

Application Codes The first column displays the application codes in an ascending order. The second column displays the name of the registered detergent or diluent. 8 characters are accepted as maximum.

- 947 NaOH-D
- 948 SMS
- 949 SCCS
- 951-957 Diluent (e.g. NaCl)
- 958-960 Diluent for development channel (open channel) applications. Diluents for development channel applications are marked with an asterisk (*)

Reagent Information Area

Name This field displays registered detergents and diluents. 8 characters are accepted as maximum.

Application Code This field displays the application code.

Cassette Code This field displays the cassette code (1-9999999). For development channel (open channel) diluents only 0777773 (**cobas c** pack MULTI cassette code) can be entered.

Expiration Days This field displays the number of days until the reagent expires.

Button

Bottle Setting Use this button to open the **Bottle Setting** window.

See *Bottle Setting window* on page E-417.

Bottle Setting window

➔ **Utility** > **System** (**Page 3/4**) > **Dil. + Cln.** > **Bottle Setting**or **Utility** > **Application** > **Analyze** > **Bottle Setting**

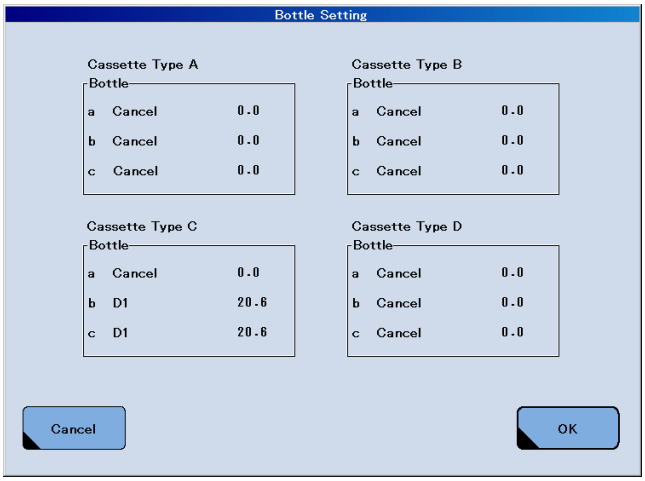


Figure E-244 Bottle Setting window

Use this window to view the bottle settings for reagent cassettes. Up to 4 different combinations of bottles are available. Parameters downloaded from **cobas** link contain the bottle setting information (A-D). When a **cobas c** pack is inserted, the system reads the bottle setting from the cassette's barcode.

Cassette Type A-D Up to 4 cassette types are available for one test application or diluent/cleaner respectively. **Cassette Type A** (COBAS INTEGRA cassette), **Cassette Type B**, **C**, **D** (small, medium, large).

See *Reagents* on page B-108.

Bottle area

The left column displays the aspiration position **a**-**c**, followed by reagent type (**R1**, **R2**, **R3**, **D1**, **D2**, **D3**, **DIL,** or **Cancel**). The right column displays the number of tests or the filling volume in ml in each of the compartments of the **cobas c** pack.

Automatic Printout Setting window

➔ **Utility** > **System** (**Page 4/4**) > **Automatic Printout**

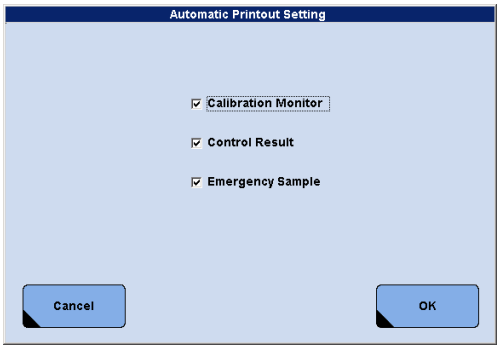


Figure E-245 Automatic Printout Setting window

This window is used to enable or disable automatic printing of quality control results, emergency (STAT) samples and the calibration monitor report.

When one of these check boxes is selected, the system prints the results from every sample of that type without any further action by the operator.

Calibration Monitor Select this check box to enable, or deselect it to disable automatic printing of the calibration monitor report.

See *Calibration Monitor report* on page E-121.

Only if the automatic printout is activated the calibration monitor for the **e** 601 is available as a printout. Later on, this calibration monitor cannot be printed again.

Control Result Select this check box to enable, or deselect it to disable automatic printing of the results from quality controls.

See *Data Monitor report (monitor format) explanation* on page E-79.

Emergency Sample Select this check box to enable, or deselect it to disable automatic printing of the results from emergency samples.

See *Data Monitor report (report format) explanation* on page E-81.

Review By Exception window

➔ **Utility** > **System** (**Page 4/4**) > **Review By Exception**

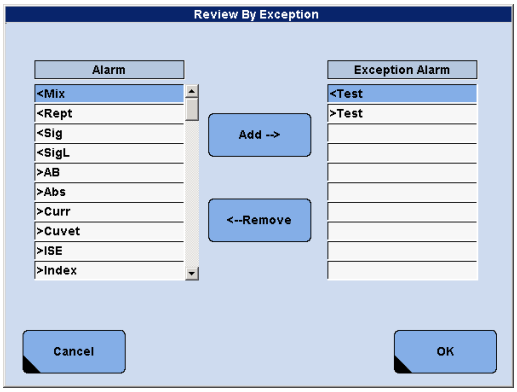


Figure E-246 Review By Exception window

Use this window to select which data alarm, if present, prevents a test result from being sent to the Host computer automatically.

Results with exception data alarms are not printed in the **Data Monitor** report, if the report is printed in the report format.

Alarm list This list displays all data alarms available for patient samples.

See *Data alarm list* on page D-10.

Exception Alarm list This list displays all data alarms selected for the exception.

If sample results are missing on the Host or in the **Data Monitor** report, checking this review by exception list is one step in the trouble shooting process.

Add--> Choose this button to add the alarm currently selected in the **Alarm** list to the **Exception Alarm** list.

<--Remove Choose this button to remove the exception alarm currently selected from the **Exception Alarm** list.

Maintenance screen

➔ **Utility** > **Maintenance**

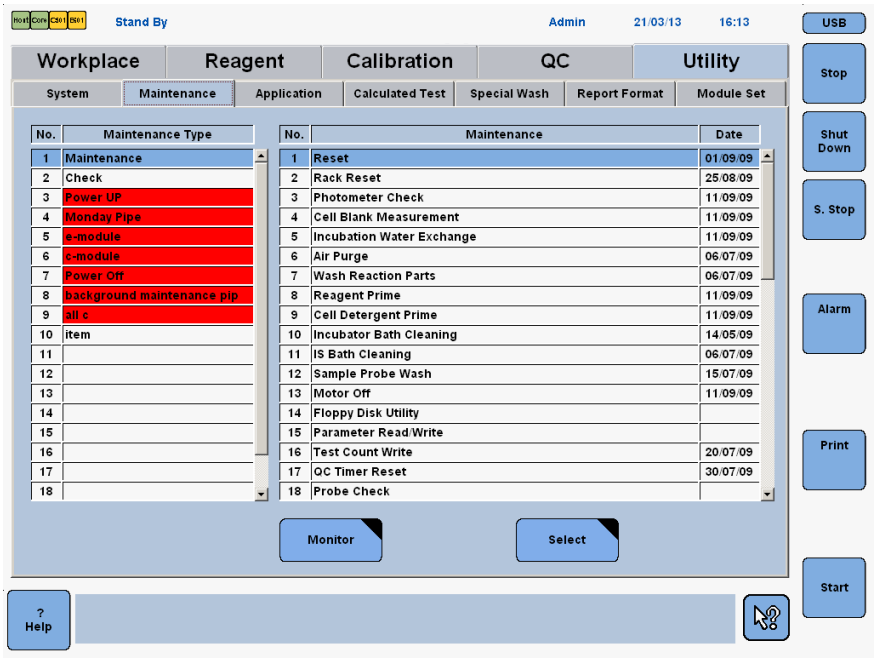


Figure E-247 Maintenance screen

This screen is used to perform maintenance functions and track maintenance.

For more information, see:
Defining and editing maintenance pipes on page C-11
Performing maintenance items or pipes on page C-13
Start Up pipe function on page C-16
Tracking maintenance on page C-21

Maintenance Type list

This list can display up to 19 maintenance types and is used to select the type of maintenance to be viewed. Up to 17 user specific maintenance types (3-19) can be defined. Types 1 and 2 are predefined. The maintenance type is highlighted in yellow if any item for this maintenance type exceeds its warning level. The maintenance type is highlighted in red if any item for this maintenance type exceeds its maintenance interval.

For more information, see *Defining and editing maintenance types* on page C-19.

Maintenance list

This list displays up to 50 maintenance items. It is used to select the maintenance or check item to be executed.

The date when the maintenance was started the last time is displayed in the **Date** column. The date in the list is highlighted in yellow if the maintenance item exceeds its warning level. The date in the list is highlighted in red if any item for this maintenance type exceeds its maintenance interval.

For individual Maintenance items, see:

Maintenance item	Page	Maintenance item	Page
1 Reset	E-424	21 Bead Mixer Rinse	E-446
2 Rack Reset	E-425	22 E module Reagent Wash	E-447
3 Photometer Check	E-426	23 Pipetter Air Purge	E-448
4 Cell Blank Measurement	E-427	24 Sipper Air Purge	E-449
5 Incubation Water Exchange	E-428	25 MC Preparation	E-450
6 Air Purge	E-429	26 MC Exchange	E-451
7 Wash Reaction Parts	E-430	27 Liquid Flow Cleaning	E-452
8 Reagent Prime	E-431	28 Inventory Update	E-453
9 Cell Detergent Prime	E-433	29 Manual Cleaning	E-454
10 Incubator Bath Cleaning	E-434	30 Pre-Wash Sipper Rinse	E-455
11 IS Bath Cleaning	E-435	31 Pre-Wash Sipper Air Purge	E-456
12 Sample Probe Wash	E-436	32 Finalization	E-457
13 Motor off	E-437	33 Empty PC/CC Reservoir	E-458
14 Floppy Disk Utility	E-438	34 Initial Bead Mixing	E-459
15 Parameter Read/Write	E-439	35 Reagent Capping	E-460
16 Test Count Write	E-441	36 AssayCup Discarding	E-461
17 QC Timer Reset	E-442	37 System Air Purge (E Module)	E-462
18 Probe Check	E-443	38 System Prime (E Module)	E-463
19 System Wash	E-444	39 Change Light Source Lamp	E-464
20 Reagent Probe Wash	E-445	40 Trace Doc Export	E-465

Table E-23 Maintenance item list

Maintenance item	Page	Maintenance item	Page
1 Check Disk	E-466	10 Reagent Pipetting Check	E-476
2 ISE Check	E-468	11 Cap Opener Check	E-477
3 Mechanisms Check	E-469	12 Bead Mixer Check	E-478
4 Sample Barcode Reader Check	E-470	13 Gripper Check	E-479
5 Reagent Barcode Reader Check	E-471	14 Magazine Exchange Check	E-480
6 Cassette Loading Check	E-472	15 Sipper Check	E-481
7 Cuvette Mixing	E-473	16 Pre-wash Probe Check	E-482
8 Reagent Short Sensor Check	E-474	17 Pre-wash Gripper Check	E-483
9 Sample Pipetting Check	E-475		

Table E-24 Maintenance check list

Buttons

Monitor Choose this button to view the status of the maintenance item being performed on the different modules.

See *Maintenance Monitor window* on page E-422.

Select Choose this button to display the maintenance item window for the selected maintenance item.

Maintenance Monitor window

➔ **Utility** > **Maintenance** > **Monitor**

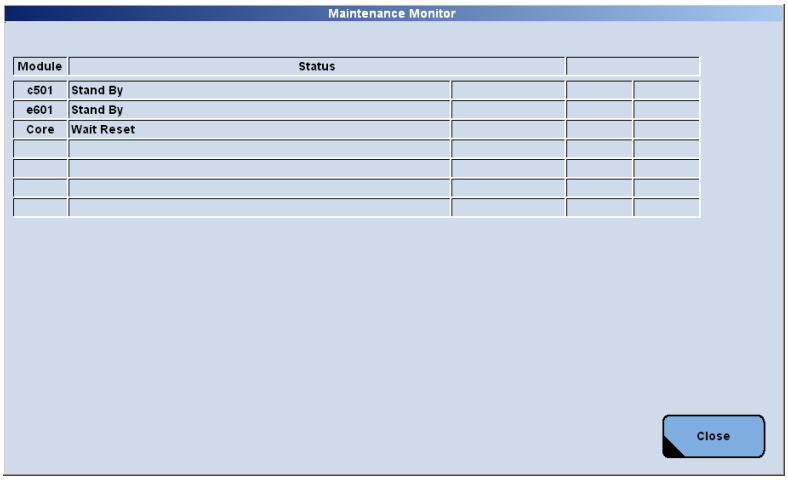


Figure E-248 Maintenance Monitor window

Use this window to view the status of the maintenance item being performed. It shows the module, the operating status of the module (**Stand By**, **Sensor Check**, etc.) and the remaining time to complete the maintenance item displayed in hours, minutes and seconds as well as a progress indicator.

Module The **Module** column displays the module on which the maintenance is being performed.

Status The **Status** column displays the status of the module on which the maintenance is being performed (for example, **Stand By**), or the maintenance action that is being performed.

Remaining Time The **Remaining Time** column displays the time remaining for the maintenance item.

Maintenance items

When **Maintenance** is selected in the **Maintenance Type** list, the following maintenance items are available in the maintenance item list for selection.

Maintenance item	Page	Maintenance item	Page
1 Reset	E-424	21 Bead Mixer Rinse	E-446
2 Rack Reset	E-425	22 E module Reagent Wash	E-447
3 Photometer Check	E-426	23 Pipetter Air Purge	E-448
4 Cell Blank Measurement	E-427	24 Sipper Air Purge	E-449
5 Incubation Water Exchange	E-428	25 MC Preparation	E-450
6 Air Purge	E-429	26 MC Exchange	E-451
7 Wash Reaction Parts	E-430	27 Liquid Flow Cleaning	E-452
8 Reagent Prime	E-431	28 Inventory Update	E-453
9 Cell Detergent Prime	E-433	29 Manual Cleaning	E-454
10 Incubator Bath Cleaning	E-434	30 Pre-Wash Sipper Rinse	E-455
11 IS Bath Cleaning	E-435	31 Pre-Wash Sipper Air Purge	E-456
12 Sample Probe Wash	E-436	32 Finalization	E-457
13 Motor off	E-437	33 Empty PC/CC Reservoir	E-458
14 Floppy Disk Utility	E-438	34 Initial Bead Mixing	E-459
15 Parameter Read/Write	E-439	35 Reagent Capping	E-460
16 Test Count Write	E-441	36 AssayCup Discarding	E-461
17 QC Timer Reset	E-442	37 System Air Purge (E Module)	E-462
18 Probe Check	E-443	38 System Prime (E Module)	E-463
19 System Wash	E-444	39 Change Light Source Lamp	E-464
20 Reagent Probe Wash	E-445	40 Trace Doc Export	E-465

Table E-25 Maintenance item list

Reset window

➔ **Utility** > **Maintenance** > **Maintenance** (**Maintenance Type**) > **(1) Reset** > **Select**

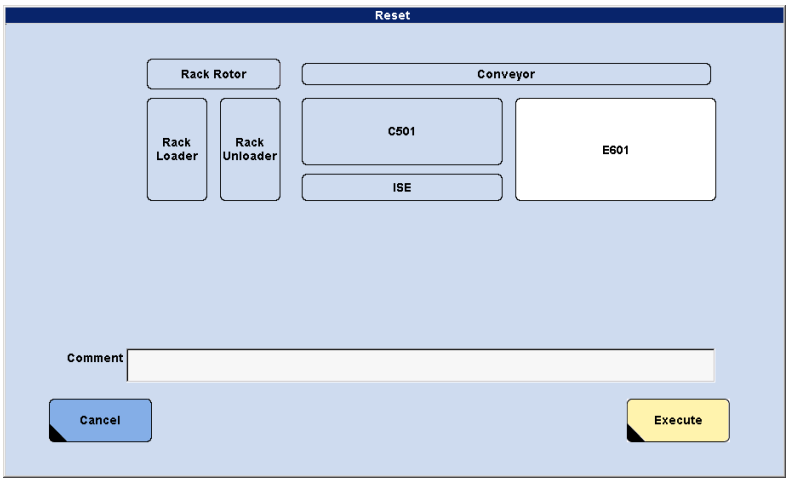


Figure E-249 Reset window

This window is used to initiate a reset for the loader, unloader, rack rotor, conveyor, and selected modules. Selected modules are highlighted white.

Actions of the following modules:

c 501 (0:24), e 601 (0:40): Mechanical parts are reset to their home positions.

cu 150: Mechanical parts are reset to their home positions, all racks are transported to the unloader.

System Layout Use the system layout to select the required module and/or unit for the current operation. Depending on the current operation following modules and units are selectable:

- **Rack Loader**
- **Rack Unloader**
- **Rack Rotor**
- **Conveyor**
- **c** 501 module
- **ISE** unit
- **e** 601 module

Selected modules are highlighted white.

Comment The comment entered in this window will be printed on the maintenance report.

Rack Reset window

➔ **Utility** > **Maintenance** > **Maintenance** (**Maintenance Type**) > **(2) Rack Reset** > **Select**

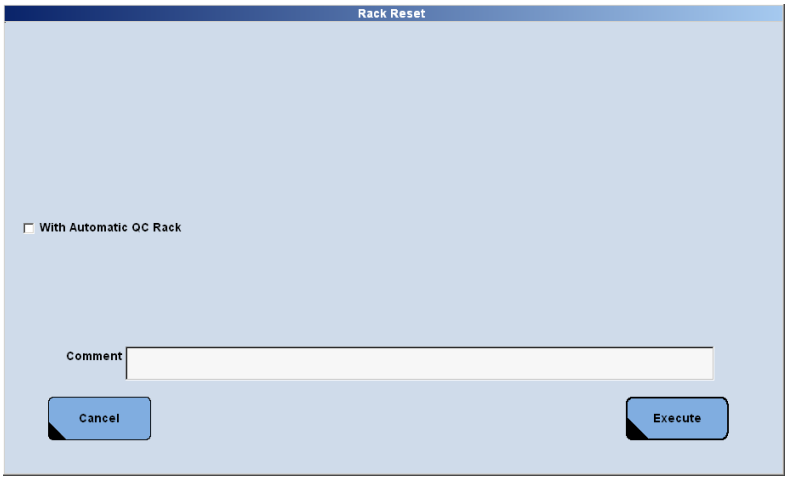


Figure E-250 Rack Reset window

Use this window to transport all racks to the unloader.

cu 150: Mechanical parts are reset to their home positions, all racks including STAT racks are transported to the unloader. When there is a rack for automatic QC in the rack rotor, it will remain in the rotor unless the check box (With Automatic QC Rack) is selected.

With Automatic QC Rack If this check box is activated, automatic QC racks are also transported to the unloader.

Comment The comment entered in this window will be printed on the maintenance report.

Photometer Check window

➔ **Utility** > **Maintenance** > **Maintenance** (**Maintenance Type**) > **(3) Photometer Check** > **Select**

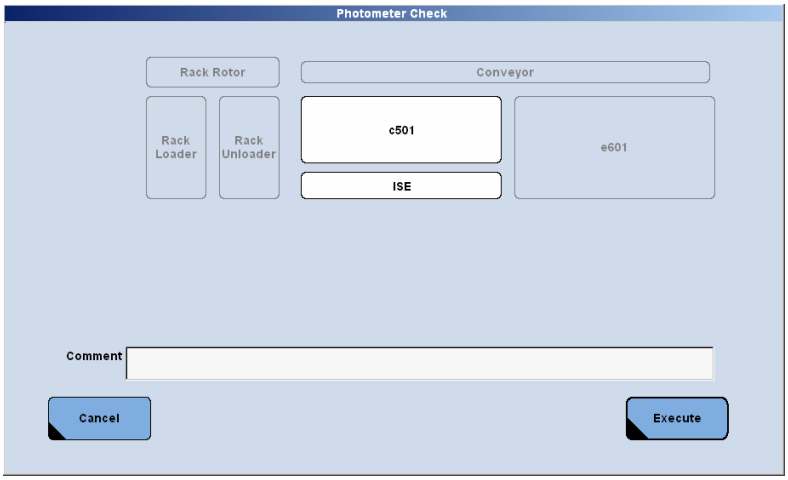


Figure E-251 Photometer Check window

Use this window to initiate a **Photometer Check** on any **c** 501 (P). Selected modules are highlighted white.

c 501 (P) (3:53): Photometer output is checked by measuring a water blank of cell no. 1. Perform this maintenance item daily. To view report, choose Print (global button) > View. Measurement results must be below 14000. If results are higher, check the light path, if necessary replace the photometer lamp, then perform cell blank measurement.

Before performing this maintenance item, check that the temperature of the incubator bath water is within 37 ±0.1 °C (98.6 ±0.2 °F). Depending on the ambient temperature it can take up to 30 minutes after switching on the analyzer or after maintenance item (5) Incubation Water Exchange for the incubator to reach the correct temperature.

👁 See *To check the light intensity* on page C-101.

Comment The comment entered in this window will be printed on the maintenance report.

Cell Blank Measurement window

➔ **Utility** > **Maintenance** > **Maintenance** (**Maintenance Type**) > **(4) Cell Blank Measurement** > **Select**

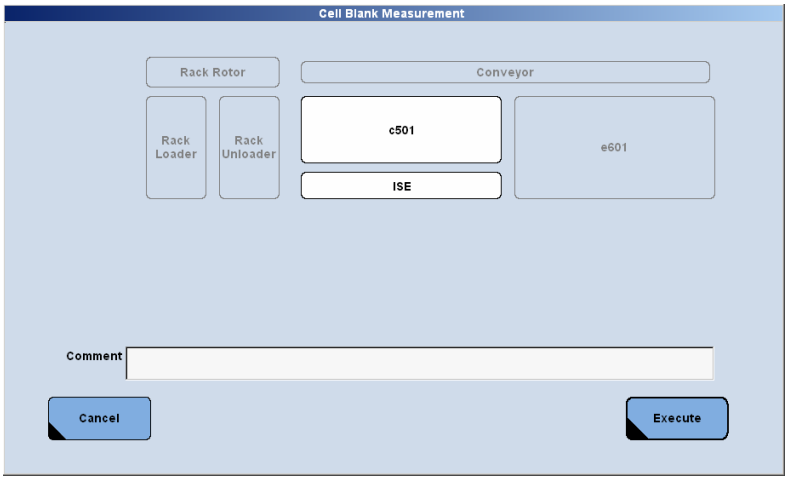


Figure E-252 Cell Blank Measurement window

Use this window to initiate a **Cell Blank** on any **c** 501 (P). Selected modules are highlighted white.

c 501 (P) (19:42): Water blanks of all cells are measured. If there is a difference greater than 0.1 absorbance units in the results for one cell compared to cell no. 1, that cell number is written to the Abnormal Cell List. To view this report choose Print (global button) > View. Perform this maintenance item weekly.

For information about the cell blank measurement, see:
To perform a cell blank measurement on page C-78
To view the cell blank measurement results on page C-79
Cell Blank Measurements report explanation on page E-166

Comment The comment entered in this window will be printed on the maintenance report.

Incubation Water Exchange window

➔ **Utility** > **Maintenance** > **Maintenance** (**Maintenance Type**) > **(5) Incubation Water Exchange** > **Select**

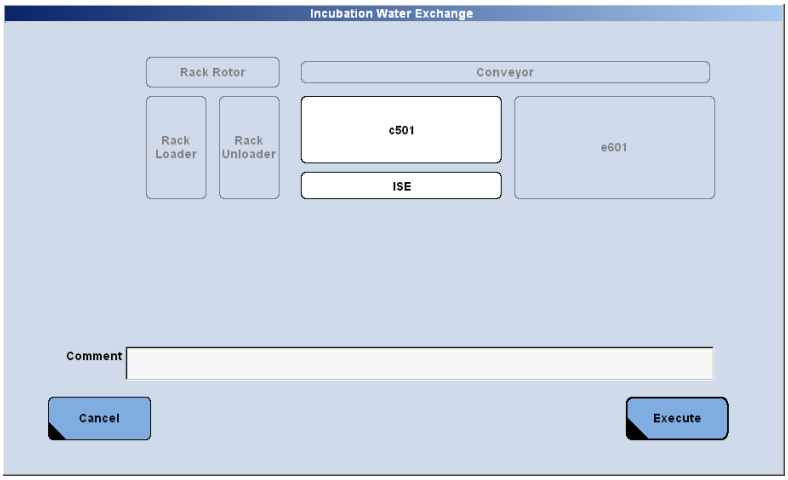


Figure E-253 Incubation Water Exchange

Use this window to initiate an **Incubation Water Exchange** on any **c** 501 (P). Selected modules are highlighted in white.

c 501 (P) (4:41): Incubator bath water is exchanged and EcoTergent (approx. 4 ml) is added. Perform this maintenance item daily. If the Incubation Water Exchange Setting check box (Utility > System) is activated, the incubator bath water is exchanged five times and approx. 8 ml EcoTergent is added. This takes 17:30 min.

After this maintenance item has been performed, check that the temperature of the incubator is within 37 ±0.1 °C (98.6 ±0.2 °F) before performing maintenance item (3) Photometer Check. Depending on the ambient temperature it can take up to 30 minutes for the incubator to reach the correct temperature.

Comment The comment entered in this window will be printed on the maintenance report.

Air Purge window

➔ **Utility** > **Maintenance** > **Maintenance** (**Maintenance Type**) > **(6) Air Purge** > **Select**

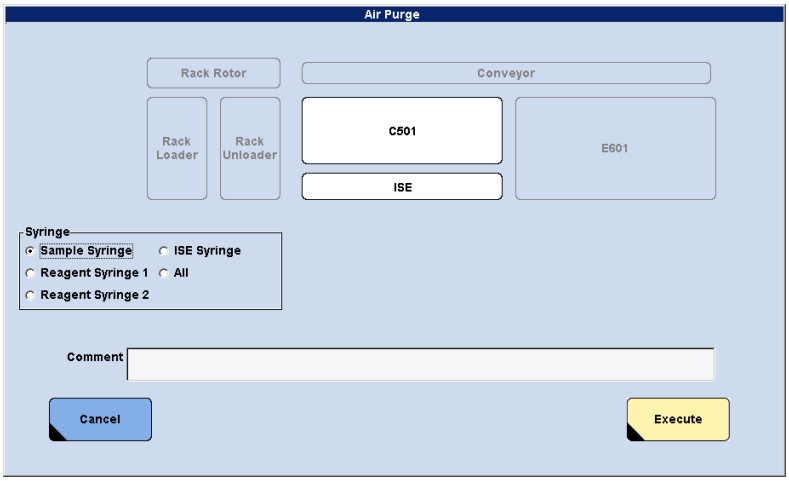


Figure E-254 Air Purge window

Use this window to initiate an **Air Purge** on any **c** 501. Selected modules are highlighted in white.

c 501 (0:52): Air is purged from sample and reagent pipetters. Perform this maintenance item daily.

Syringe area The option button of sample syringe is already selected. If another option is needed, click the corresponding button.

Comment The comment entered in this window will be printed on the maintenance report.

Wash Reaction Parts window

➔ **Utility** > **Maintenance** > **Maintenance** (**Maintenance Type**) > **(7) Wash Reaction Parts** > **Select**

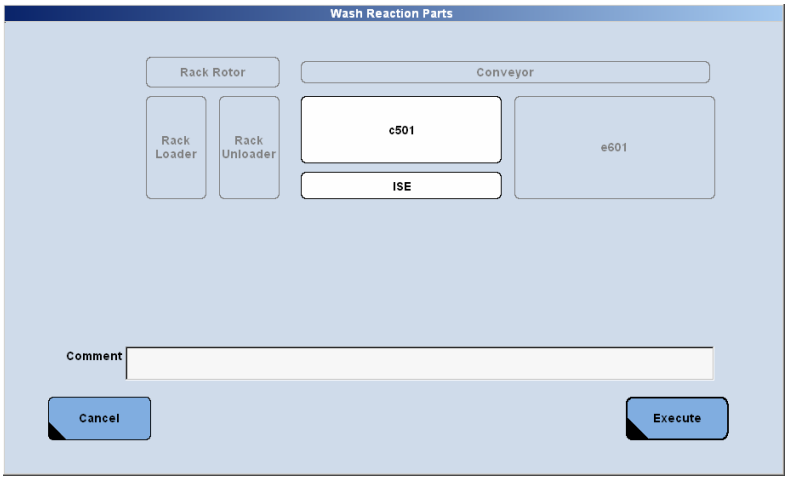


Figure E-255 Wash Reaction Parts window

Use this window to initiate a **Reaction Parts Wash** on any **c** 501 (P). Selected modules are highlighted in white.

c 501 (P) (35:00): All cells and reagent probes are washed. The sample probe is washed with Sample Cleaner 1 (approx. 1 ml). The reagent probes and cells are washed with detergent from a detergent cassette (approx. 58 ml NaOH-D, application code 947).

For more information, see:
To rinse the reaction system on page C-78
To perform a cell blank measurement on page C-78

Comment The comment entered in this window will be printed on the maintenance report.

Reagent Prime window

➔ **Utility** > **Maintenance** > **Maintenance** (**Maintenance Type**) > **(8) Reagent Prime** > **Select**

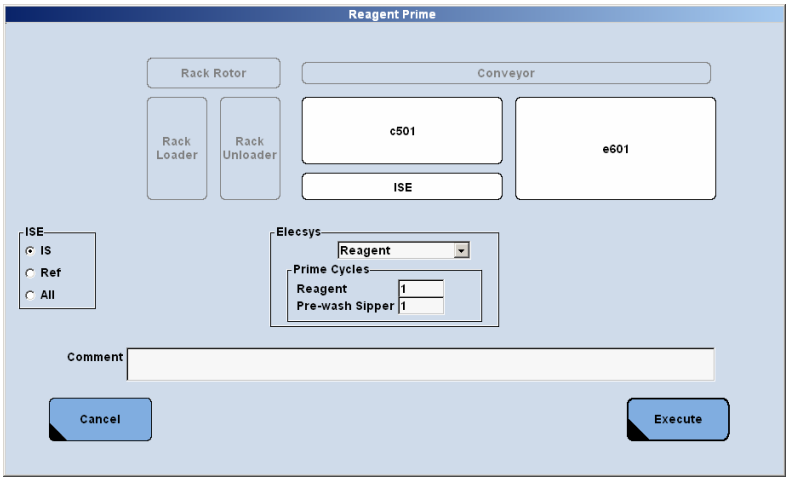


Figure E-256 Reagent Prime window

There are three ways to access this window.

- **System Overview** > **Reagent Prime** (**Work Flow** area)
- **Reagent** > **Reagent Prime**
- **Utility** > **Maintenance** > **Maintenance** (**Maintenance Type**) > **(8) Reagent Prime** > **Select**

This window is used to initiate a prime of the auxiliary reagents on the modules. Performing a reagent prime substitutes the liquid in the tubing. A reagent prime ensures that there is no air in the reagent tubing.

c 501 (ISE): Reagents are primed according to the chosen option (IS, Ref, or All).

Options	System time	Description	Reagent consumption
IS	4:35	ISE IS is aspirated through the sipper to prime the measurement cartridges.	ISE IS: 6.6 ml ISE Ref.: 0.8 ml
Ref	2:34	ISE Ref. is aspirated through the reference cartridge to prime the reference electrode.	ISE IS: 0 ml ISE Ref.: 9.0 ml
All	6:44	Both ISE IS and ISE Ref. are primed.	ISE IS: 6.6 ml ISE Ref.: 9.8 ml

Table E-26 **c** 501 reagent prime options

e 601: If Reagent is selected the tubings of ProCell and CleanCell are primed and air bubbles are washed out of the system by emptying the reservoirs and refilling them. If Pre-wash Sipper is selected the PreClean tubings are primed and air bubbles are washed out of the system.

For details on operation procedures, see:
Reagent Preparing button on page B-44
c 501 – ISE unit on page B-45
e 601 on page B-50
Reagent reloading (e 601) on page B-128
To perform a Reagent Prime on page B-48
To replace ISE IS or ISE Dil. on page B-46
To replace ISE reference solution (ISE Ref.) on page B-47

System Layout Use the system layout to select the module(s) on which the reagent prime will be performed. Selected modules are highlighted white.

Comment The comment entered in this window will be printed on the maintenance report.

ISE area

The **ISE** area displays different types of prime: Internal Standard (**IS**), Reference Solution (**Ref**) and **All**.

If you have replaced an ISE IS or ISE Ref. bottle, it is necessary to perform a reagent prime for the ISE. After the Reagent Prime, recalibrate the ISE unit before you resume routine operation.

IS Select the **IS** option to prime the internal standard solution.

Ref Select the **Ref** option to prime the reference solution.

All Select the **All** option to prime both the reference and the internal standard solution.

Elecsys area

E601 Select the auxiliary reagent that is to be primed from this list box.

- **Reagent**: Select this option to prime the ProCell and CleanCell flow path and reservoirs.
- **Pre-wash Sipper**: Select this option to prime the PreClean sippers of an **e** 601 module.

Prime Cycles Use this text box to enter the number of reagent prime cycles (1 to 9999) and the number of pre-wash sipper cycles to be performed.

Comment The comment entered in this window will be printed on the maintenance report.

Cell Detergent Prime window

➔ **Utility** > **Maintenance** > **Maintenance** (**Maintenance Type**) > **(9) Cell Detergent Prime** > **Select**

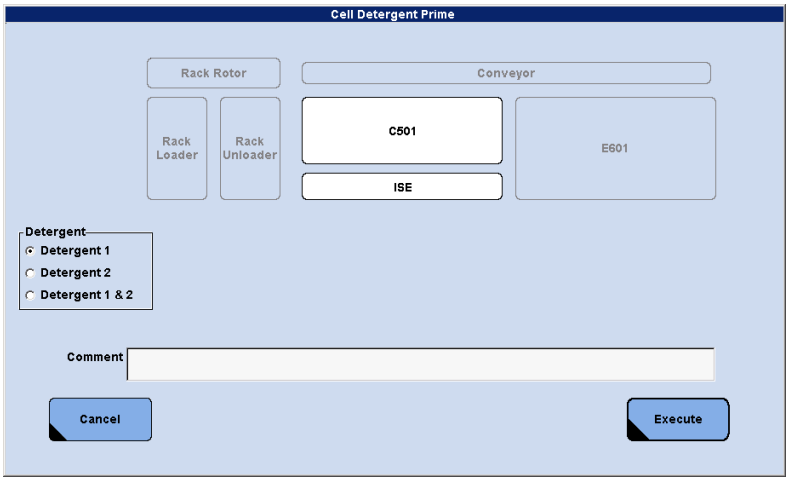


Figure E-257 Cell Detergent Prime window

Use this window to initiate a **Cell Detergent Prime** on the **c** 501 (P). Selected modules are highlighted in white.

c 501 (P) (7:30): Reagent lines for Cell Wash Solution I / NaOH-D and Cell wash Solution II / Acid Wash are primed (30 times); reagent lines are purged of air and cells are filled up and emptied by vacuum.

Detergent area In the **Detergent** setting box choose the detergent that is needed to be primed.

See *To perform a cell detergent prime* on page C-95.

Comment The comment entered in this window will be printed on the maintenance report.

Incubator Bath Cleaning window

➔ **Utility** > **Maintenance** > **Maintenance** (**Maintenance Type**) > **(10) Incubator Bath Cleaning** > **Select**

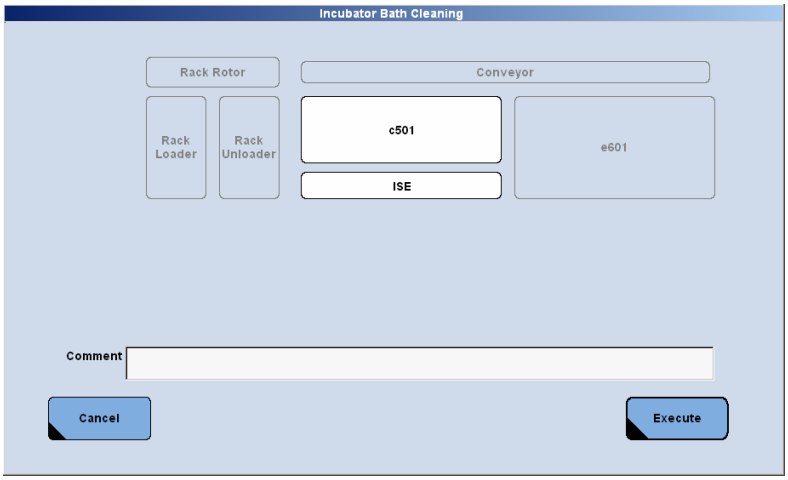


Figure E-258 Incubator Bath Cleaning window

Use this window to initiate an **Incubator Bath Cleaning** on the **c** 501 (P). Selected modules are highlighted in white.

c 501 (P): Performs transition to incubator bath cleaning mode: The photometer lamp is switched off and the incubator bath water is automatically drained. Cleaning of ultrasonic mixers or incubator bath is possible without complete system shutdown. Choose Continue on the Utility > Maintenance >Incubator Bath Cleaning window to end the incubator bath cleaning mode; the incubator bath is automatically refilled with water and EcoTergent (approx. 4 ml).

Comment The comment entered in this window will be printed on the maintenance report.

IS Bath Cleaning window

➔ **Utility** > **Maintenance** > **Maintenance** (**Maintenance Type**) > **(11) IS Bath Cleaning** > **Select**

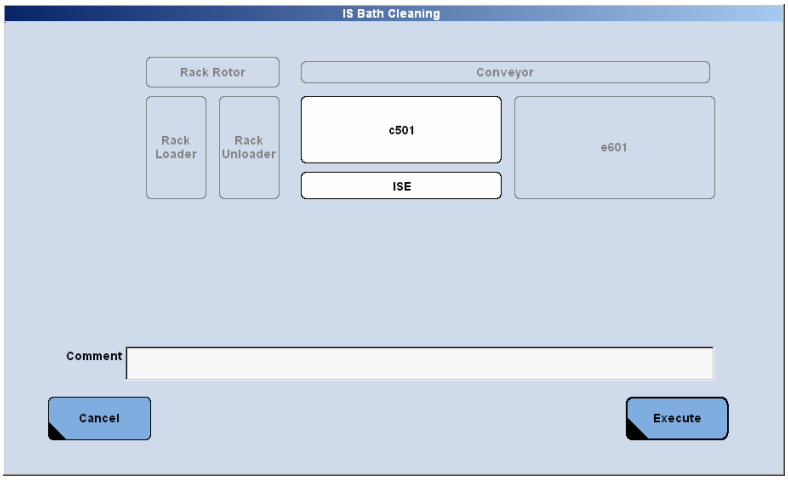


Figure E-259 IS Bath Cleaning window

Use this window to initiate an **IS Bath Cleaning** on the **c** 501 (P). Selected modules are highlighted in white.

c 501 (ISE) (1:35): The IS bath is rinsed. Perform this maintenance daily. However, this is not necessary after processing a green rack (flow path washing) because IS bath cleaning is already included in that maintenance.

Comment The comment entered in this window will be printed on the maintenance report.

Sample Probe Wash window

➔ **Utility** > **Maintenance** > **Maintenance** (**Maintenance Type**) > **(12) Sample Probe Wash** > **Select**

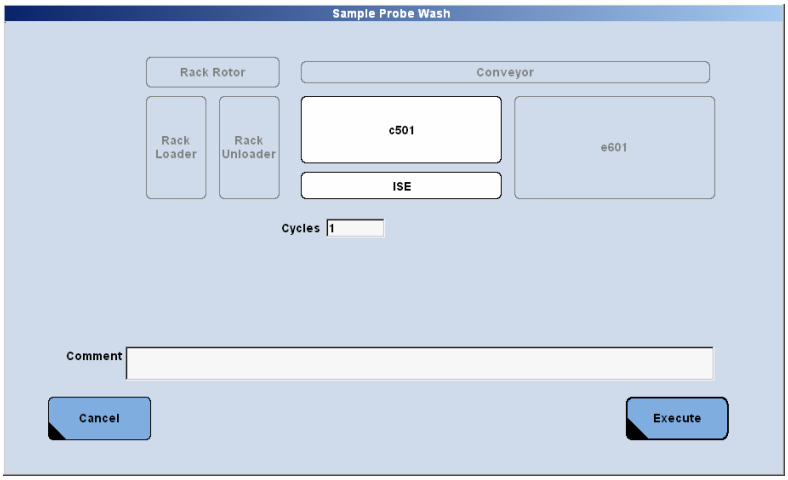


Figure E-260 Sample Probe Wash window

Use this window to initiate a **Sample Probe Wash** on the **c** 501 (P). Selected modules are highlighted in white.

c 501: The sample probe is washed with Sample Cleaner 1. This item can be used in case of a clogged probe.

Cycles This field displays the default washing cycle 1.

Comment The comment entered in this window will be printed on the maintenance report.

Motor off window

➔ **Utility** > **Maintenance** > **Maintenance** (**Maintenance Type**) > **(13) Motor Off** > **Select**

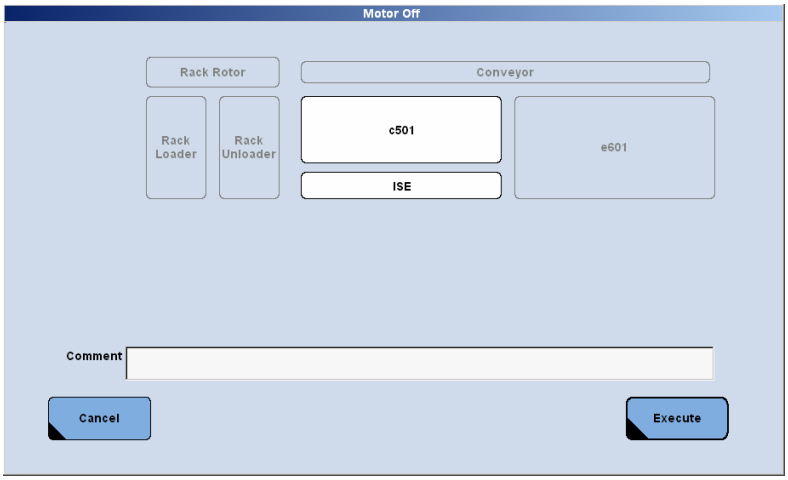


Figure E-261 Motor off window

Use this window to initiate a **Motor off** on the **c** 501 (P). Selected modules are highlighted in white.

c 501: The motors of the c 501 module are switched off. Use this item to manually move different parts, such as reagent gripper or reaction disk, without having to shut down the analyzer. If you open the top cover of the c 501 module, the motors of the module are also switched off.

Comment The comment entered in this window will be printed on the maintenance report.

Floppy Disk Utility window

➔ **Utility** > **Maintenance** > **Maintenance** (**Maintenance Type**) > **(14) Floppy Disk Utility** > **Select**

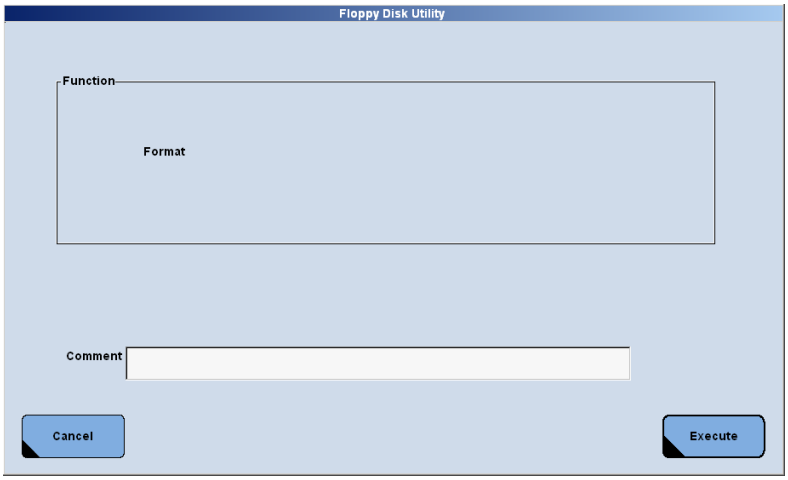


Figure E-262 Floppy Disk Utility window

This window is used to format floppy disks.

Control unit: A floppy disk inserted into the floppy disk drive will be formatted after confirmation.

Use only double-sided high density disks. All data stored on the floppy disk are lost when formatting. You cannot perform any other tasks on the system until the formatting is complete.

Comment The comment entered in this window will be printed on the maintenance report.

Parameter Read/Write window

➔ **Utility** > **Maintenance** > **Maintenance** (**Maintenance Type**) > **(15) Parameter Read/Write** > **Select**

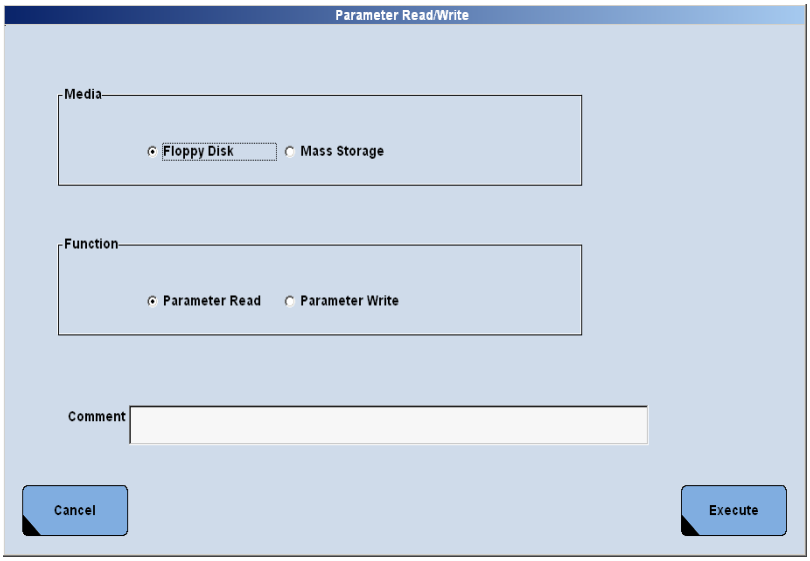


Figure E-263 Parameter Read/Write window

This window is used to read or write parameters such as application data, carryover evasion settings and maintenance pipe settings from or to a storage medium.

Control unit: Parameter settings are read from or written to a storage medium.

Data which are already present on the system or on the storage medium are overwritten with the new data. If the system is writing parameter data from the computer onto the storage medium with the **Parameter Write** option, the previous data on the storage medium (if any) are deleted. Only the newly copied data are available. The same applies to the reverse process with the **Parameter Read** option.

Comment The comment entered in this window will be printed on the maintenance report.

Media area

Use this area to set, which storage medium is used for backing up or restoring.

Option	Description
Floppy Disk	Select this option to write or read parameters from or to a floppy disk.
Mass Storage	Select this option to write or read parameters from or to a mass storage. If a **USB** storage device is inserted, the instrument uses the USB as mass storage. If no USB storage device is inserted, the instrument uses a DVD disk as mass storage.

Table E-27 Media area

For information on mass storage media, see *Data storage* on page B-244.

Function area

Use this area to set, if the parameters are backed up or if they are restored.

Option	Description
Parameter Read	**Restore**: Select this option to read parameters into the system from a media.
Parameter Write	**Backup**: Select this option to write parameters from the system onto a media.

Table E-28 Function area



Data which are already present on the system or on the storage medium are overwritten with the new data. If the system is writing parameter data from the computer onto the storage medium with the **Parameter Write** option, the previous data on the storage medium (if any) are deleted. Only the newly copied data are available. The same applies to the reverse process with the **Parameter Read** option.

Test Count Write window

➔ **Utility** > **Maintenance** > **Maintenance** (**Maintenance Type**) > **(16) Test Count Write** > **Select**

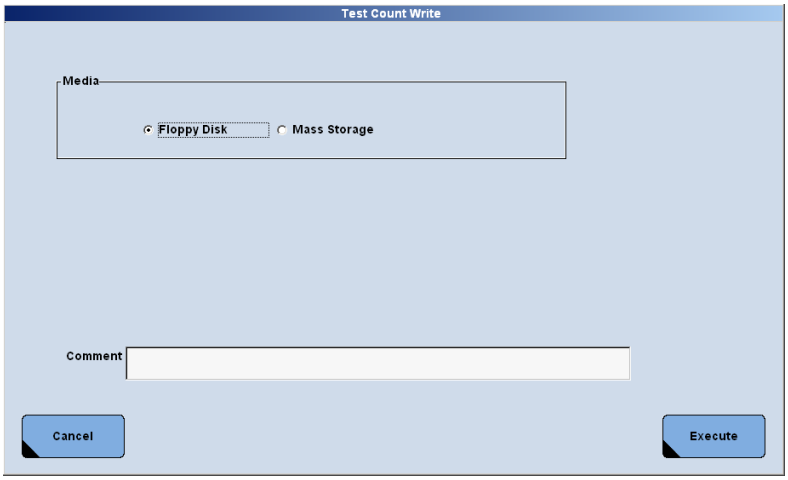


Figure E-264 Test Count Write window

This maintenance function is used to write test count information to a storage medium. This is the same information as contained in the **Cumulative Operations List** report.

See *Cumulative Operation List* on page E-158.

c 501, e 601: Test count for all modules and measuring cells is written to a storage medium.

Comment The comment entered in this window will be printed on the maintenance report.

Media area

Use this area to set, which storage medium is used for writing the test count information.

Option	Description
Floppy Disk	Select this option to write the test count information to a floppy disk.
Mass Storage	Select this option to write the test count information to a mass storage. If a **USB** storage device is inserted, the instrument uses the USB as mass storage. If no USB storage device is inserted, the instrument uses a DVD disk as mass storage.

Table E-29 Media area

For information on mass storage media, see *Data storage* on page B-244.

QC Timer Reset window

➔ **Utility** > **Maintenance** > **Maintenance** (**Maintenance Type**) > **(17) QC Timer Reset** > **Select**

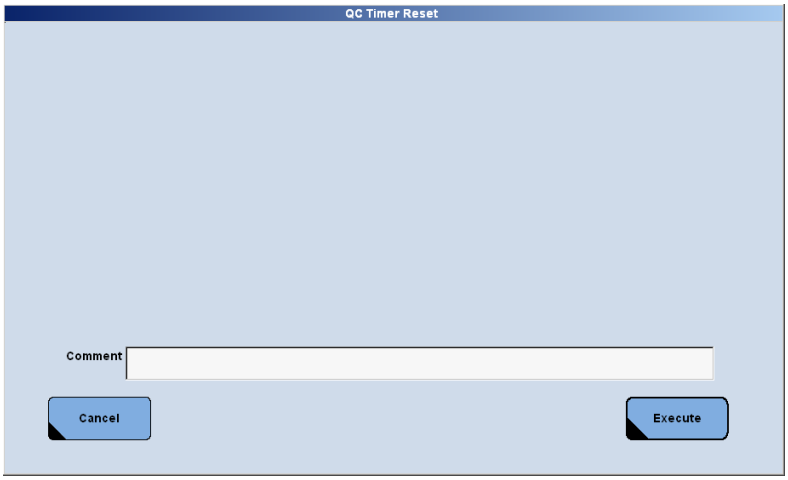


Figure E-265 QC Timer Reset window

Use this window to reset a QC Timer.

c 501 (P), e 601: Resets the control interval timer.

For example, the control interval timer is set to 10 hours. When 5 hours are left, the user can reset the timer to 10 hours.

Comment The comment entered in this window will be printed on the maintenance report.

Probe Check window

➔ **Utility** > **Maintenance** > **Maintenance** (**Maintenance Type**) > **(18) Probe Check** > **Select**

This maintenance action can only be performed by specially trained operators.

For more information, refer to the separate maintenance manual *Interlock function cobas* **c** 501 *with ISE.*

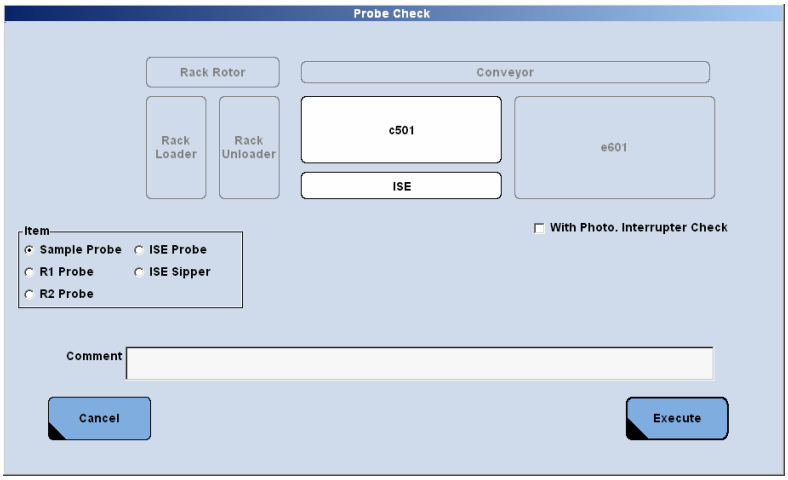


Figure E-266 Probe Check window

Use this window to initiate a **Probe Check** on the **c** 501. Selected modules are highlighted in white.

c 501: Puts the c 501 module in probe adjust mode: In this mode, a probe—selected in the Probe Adjust window—can be moved to designated positions using the maintenance key. This maintenance item should only be used by specially trained operators to verify alignment of the probe.

Item area Use this area to select a sample probe, a reagent probe or ISE probe.

With Photo. Interrupter Check If the check box With Photo Interrupter check is selected, the system checks automatically all relevant photo coupler sensors during this maintenance function. Only the defective sensors are shown in the print view screen.

Comment The comment entered in this window will be printed on the maintenance report.

System Wash window

➔ **Utility** > **Maintenance** > **Maintenance** (**Maintenance Type**) > **(19) System Wash** > **Select**

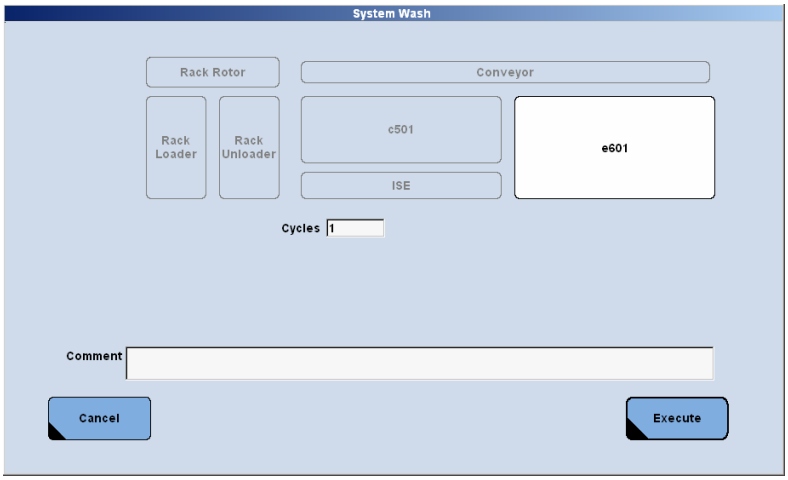


Figure E-267 System Wash window

Use this window to initiate a **System Wash** on the **e** 601. Selected modules are highlighted in white.

e 601: Combination of maintenance items (20) Reagent Probe Wash, (21) Bead Mixer Rinse, and (22) E Module Reagent Wash is performed as many times as specified.

Cycles Use this text box to enter the number of wash cycles to be performed for the **e** 601.

Reagent Probe Wash window

➔ **Utility** > **Maintenance** > **Maintenance** (**Maintenance Type**) > **(20) Reagent Probe Wash** > **Select**

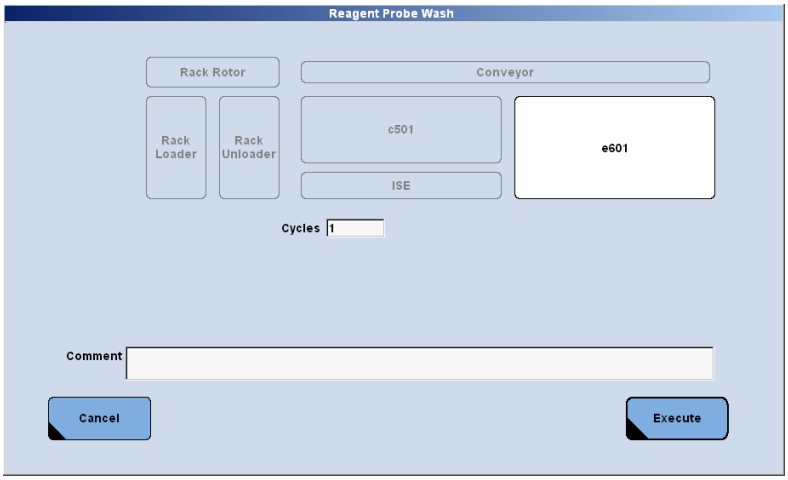


Figure E-268 Reagent Probe Wash window

Use this window to initiate a **Reagent Probe Wash** on the **e** 601 and set the number of cycles. Selected modules are highlighted in white.

e 601: Both the inside (by aspirating the ProbeWash solution) and outside of the reagent pipetter probe is washed as many times as specified.

Cycles Use this text box to enter the number of wash cycles to be performed (1 to 9999).

Comment The comment entered in this window will be printed on the maintenance report.

Bead Mixer Rinse window

➔ **Utility** > **Maintenance** > **Maintenance** (**Maintenance Type**) > **(21) Bead Mixer Rinse** > **Select**

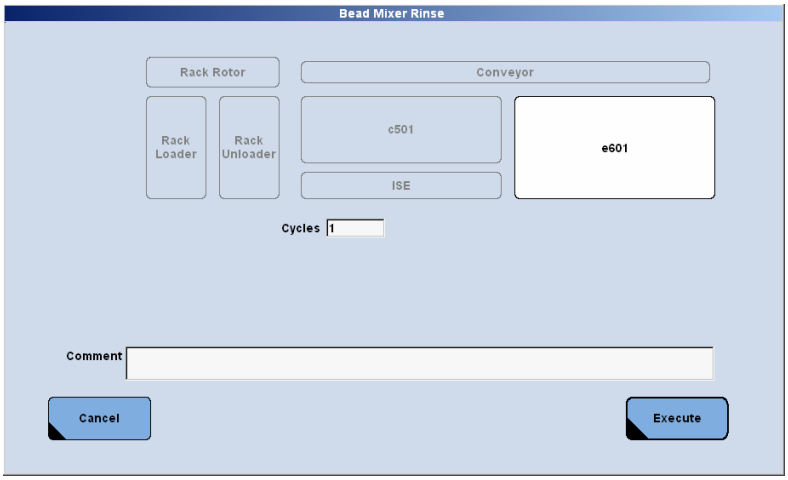


Figure E-269 Bead Mixer Rinse window

Use this window to initiate a **Bead Mixer Rinse** on the **e** 601 and set number of cycles. Selected modules are highlighted in white.

e 601: The microbead mixer is rinsed as many times as specified.

For more information about the instrument, see *Microbead mixer with rinse station* on page A-98.

Cycles Use this text box to enter the number of rinse cycles to be performed (1 to 9999).

Comment The comment entered in this window will be printed on the maintenance report.

E module Reagent Wash window

➔ **Utility** > **Maintenance** > **Maintenance** (**Maintenance Type**) > **(22) E Module Reagent Wash** > **Select**

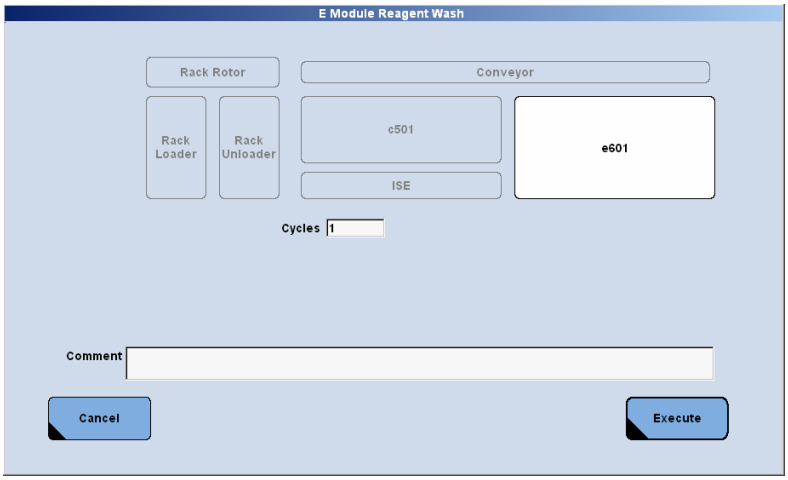


Figure E-270 E module Reagent Wash window

Use this window to initiate an **e** 601 **Reagent Wash** on the selected **e** 601 and set number of cycles. Selected modules are highlighted white.

e 601: The auxiliary reagent flow paths and the reservoirs for both ProCell and CleanCell are rinsed. That is, remaining liquid is aspirated from the reservoirs and discharged to the washing stations. Then, the auxiliary reagent flow paths and reservoirs are filled with water.

The sippers aspirate liquid in the reservoirs and discharge it to the washing stations as many times as necessary to drain the whole liquid of the reservoirs.

Afterwards (38) System Prime (E Module) and (32) Finalization should be performed.

Cycles Use this text box to enter the number of wash cycles to be performed (1 to 9999).

Comment The comment entered in this window will be printed on the maintenance report.

Pipetter Air Purge window

➔ **Utility** > **Maintenance** > **Maintenance** (**Maintenance Type**) > **(23) Pipetter Air Purge** > **Select**

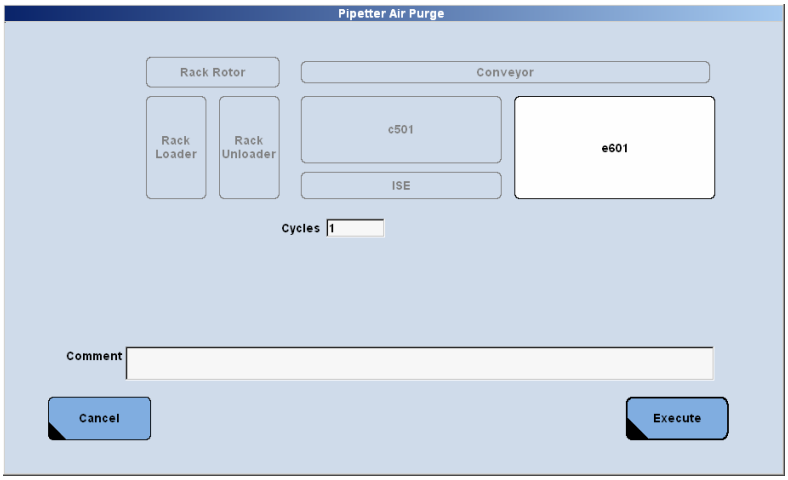


Figure E-271 Pipetter Air Purge window

Use this window to initiate a **Pipetter Air Purge** on the **e** 601 and set the number of cycles. Selected modules are highlighted in white.

e 601: Sample pipetter and reagent pipetter flow paths are purged of air as many times as specified.

Cycles Use this text box to enter the number of cycles to be performed (1 to 9999).

Comment The comment entered in this window will be printed on the maintenance report.

Sipper Air Purge window

➔ **Utility** > **Maintenance** > **Maintenance** (**Maintenance Type**) > **(24) Sipper Air Purge** > **Select**

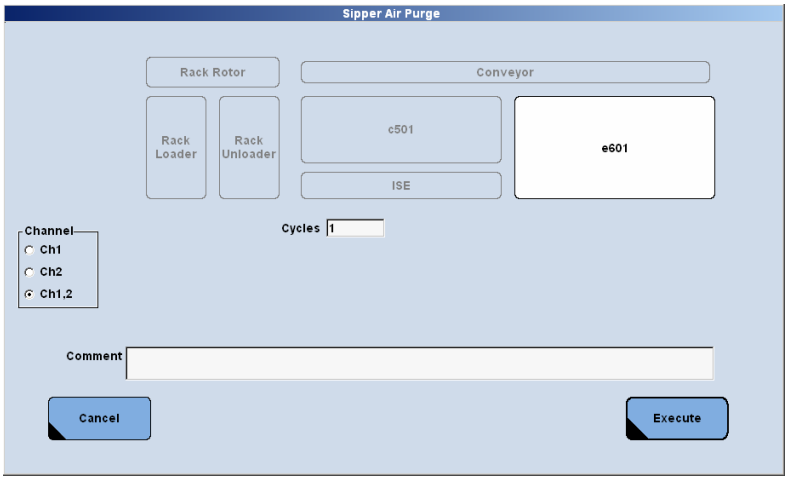


Figure E-272 Sipper Air Purge window

Use this window to initiate a **Sipper Air Purge** on the **e** 601 and measuring channel. Selected modules are highlighted in white.

e 601: Sipper flow paths are purged of air as many times as specified.

Cycles Use this text box to enter the number of cycles to be performed (1 to 9999).

Comment The comment entered in this window will be printed on the maintenance report.

Channel area

Use this area to specify a measuring channel.

Ch1 Select the **Ch1** option for measuring channel 1.

Ch2 Select the **Ch2** option for measuring channel 2.

Ch1, 2 Select the **Ch1,2** option for both measuring channels.

MC Preparation window

➔ **Utility** > **Maintenance** > **Maintenance** (**Maintenance Type**) > **(25) MC Preparation** > **Select**

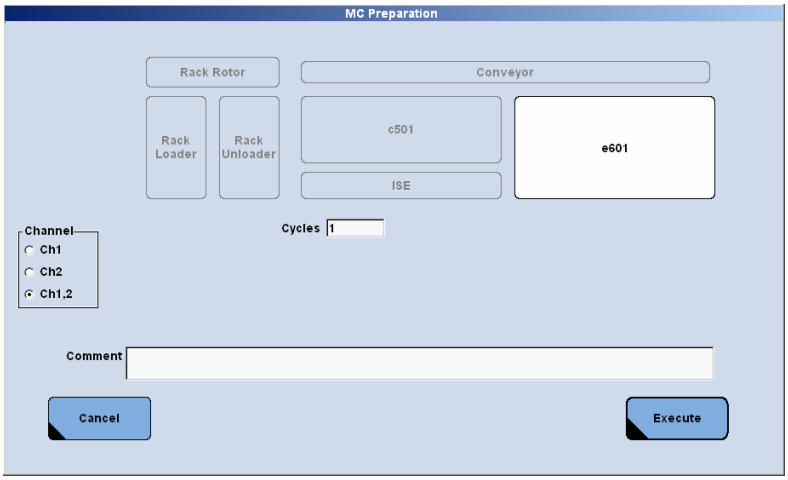


Figure E-273 MC Preparation window

Use this window to initiate a **MC Preparation** on the **e** 601 and measuring channel. Selected modules are highlighted in white.

e 601: Measuring cells are conditioned as many times as specified.

Cycles Use this text box to enter the number of wash cycles to be performed (1 to 9999).

Comment The comment entered in this window will be printed on the maintenance report.

Channel area

Use this area to specify a measuring channel.

Ch1 Select this option for measuring channel 1.

Ch2 Select this option for measuring channel 2.

Ch1, 2 Select this option for both measuring channels.

MC Exchange window

➔ **Utility** > **Maintenance** > **Maintenance** (**Maintenance Type**) > **(26) MC Exchange** > **Select**

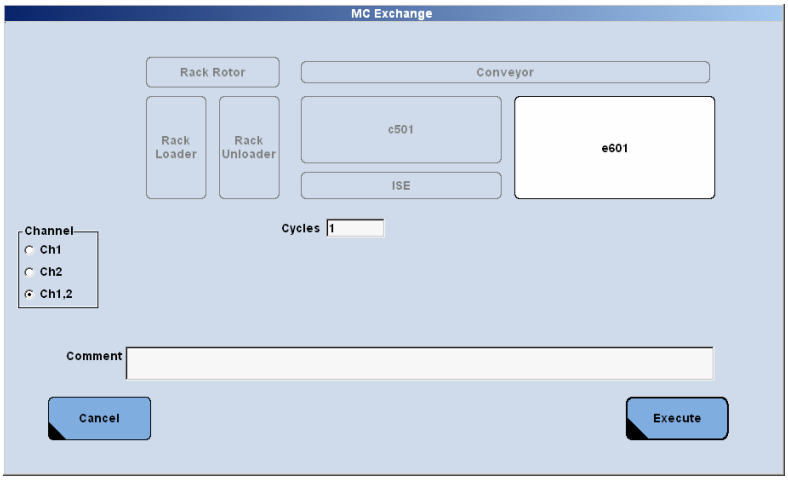


Figure E-274 MC Exchange window

Use this window to initiate a **MC Exchange** on the **e** 601 and measuring channel. Selected modules are highlighted in white.

e 601: Sipper flow paths are rinsed with water as many times as specified and then emptied to be prepared for a measuring cell exchange.

Cycles Use this text box to enter the number of wash cycles to be performed (1 to 9999).

Comment The comment entered in this window will be printed on the maintenance report.

Channel area

Use this area to specify a measuring channel.

Ch1 Select this option for measuring channel 1.

Ch2 Select this option for measuring channel 2.

Ch1, 2 Select this option for both measuring channels.

Liquid Flow Path Cleaning window

➔ **Utility** > **Maintenance** > **Maintenance** (**Maintenance Type**) > **(27) Liquid Flow Cleaning** > **Select**

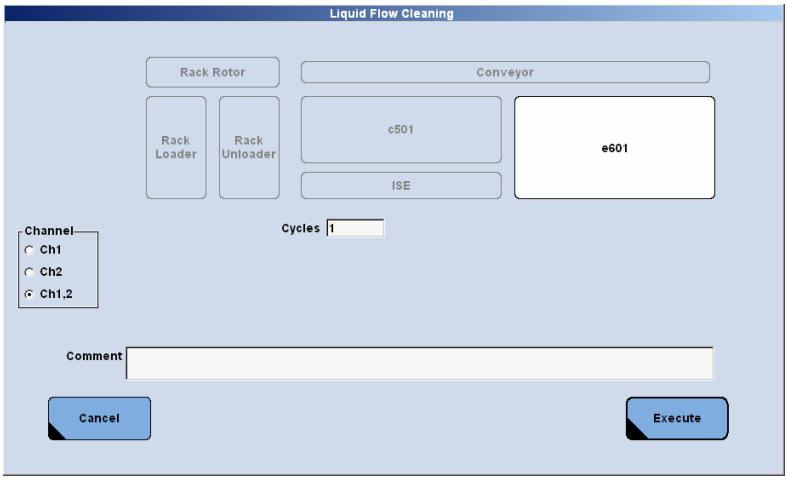


Figure E-275 Liquid Flow Path Cleaning window

Use this window to initiate a **Liquid Flow Path Cleaning** on the **e** 601 and measuring channel. Selected modules are highlighted in white.

e 601: Sipper flow paths are washed with SysClean. Liquid flow path cleaning must be performed at least once every two weeks or after 2500 to 3000 determinations per measuring cell.

Channel area

Use this area to specify a measuring channel.

Ch1 Select this option for measuring channel 1.

Ch2 Select this option for measuring channel 2.

Ch1, 2 Select this option for both measuring channels.

Cycles Use this text box to enter the number of wash cycles to be performed (1 to 3).

Comment The comment entered in this window will be printed on the maintenance report.

Inventory Update window

➔ **Utility** > **Maintenance** > **Maintenance** (**Maintenance Type**) > **(28) Inventory Update** > **Select**

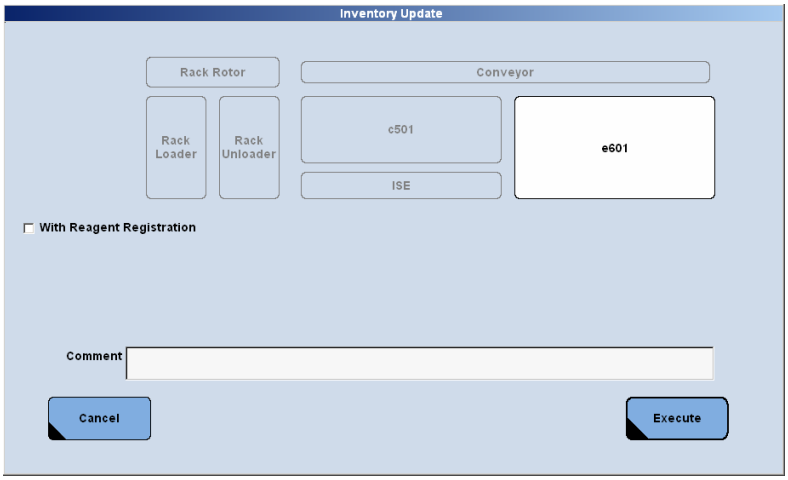


Figure E-276 Inventory Update window

Use this window to initiate an **Inventory Update** on the **e** 601. Selected modules are highlighted in white.

e 601: The number of magazines with AssayTips and AssayCups in the loading area and empty magazines in the waste area are updated.

With Reagent Registration Select this check box to initiate a reagent registration as part of the inventory update.

Comment The comment entered in this window will be printed on the maintenance report.

Manual Cleaning window

➔ **Utility** > **Maintenance** > **Maintenance** (**Maintenance Type**) > **(29) Manual Cleaning** > **Select**

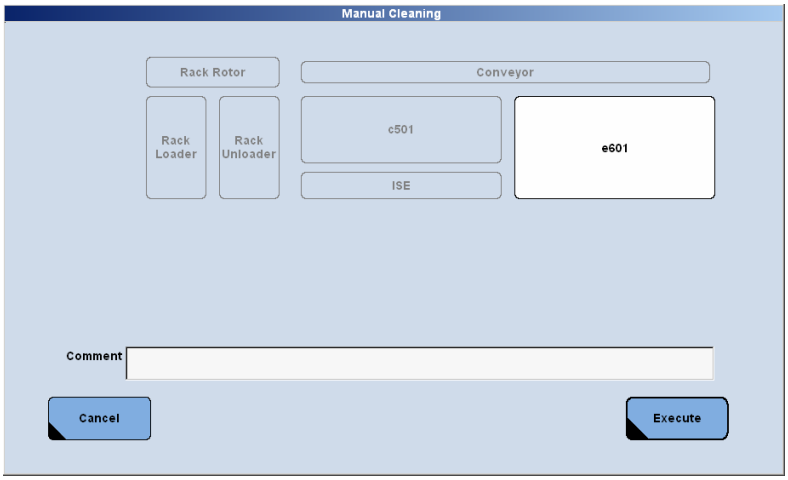


Figure E-277 Manual Cleaning window

Use this window to initiate a **Manual Cleaning** procedure on the **e** 601. Selected modules are highlighted in white.

e 601: Sample pipetter, reagent pipetter, microbeads mixer, and sippers are reset and move to positions where manual cleaning of these parts can be done. The instrument stays in the maintenance function Manual Cleaning until the Stop (global button) or Cancel Maintenance on System Overview screen is chosen.

To reset all moving parts to their home position, perform a Reset (maintenance item 10).

See *Reset window* on page E-424.

Comment The comment entered in this window will be printed on the maintenance report.

Pre-wash Sipper Rinse window

➔ **Utility** > **Maintenance** > **Maintenance (Maintenance Type)** > **(30) Pre-wash Sipper Rinse** > **Select**

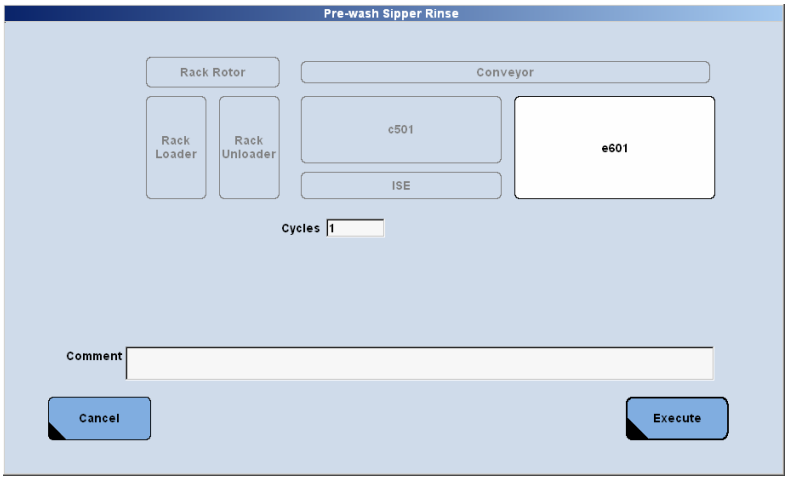


Figure E-278 Pre-wash Sipper Rinse window

Use this window to initiate a **Pre-wash Sipper Rinse** on the **e** 601 and set the number of wash cycles. Selected modules are highlighted in white.

e 601: Pre-wash Sippers are rinsed in the wash station as many times as specified.

Cycles Use this text box to enter the number of wash cycles to be performed (1 to 9999).

Comment The comment entered in this window will be printed on the maintenance report.

Pre-wash Sipper Air Purge window

➔ **Utility** > **Maintenance** > **Maintenance (Maintenance Type)** > **(31) Pre-wash Sipper Air Purge** > **Select**

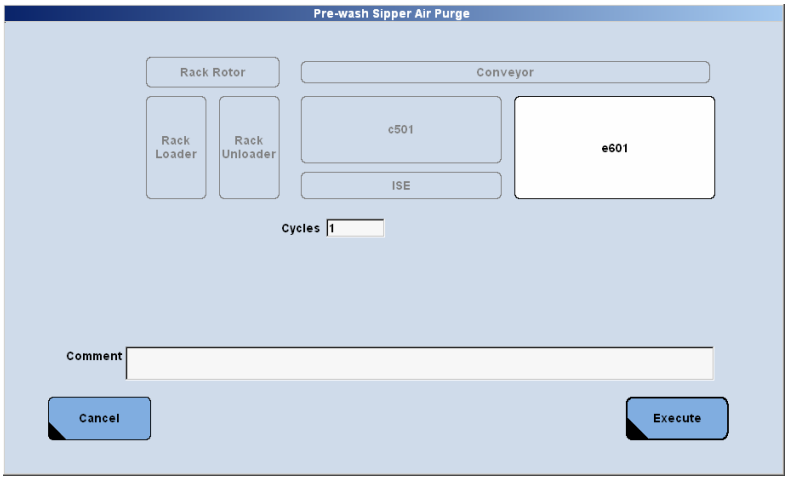


Figure E-279 Pre-wash Sipper Air Purge window

Use this window to initiate a **Pre-wash Sipper Air Purge** on the **e** 601 and set the number of cycles. Selected modules are highlighted in white.

e 601: Pre-wash Sipper flow paths are purged of air.

Cycles Use this text box to enter the number of wash cycles to be performed (1 to 9999).

Comment The comment entered in this window will be printed on the maintenance report.

Finalization window

➔ **Utility** > **Maintenance** > **Maintenance** (**Maintenance Type**) > **(32) Finalization** > **Select**

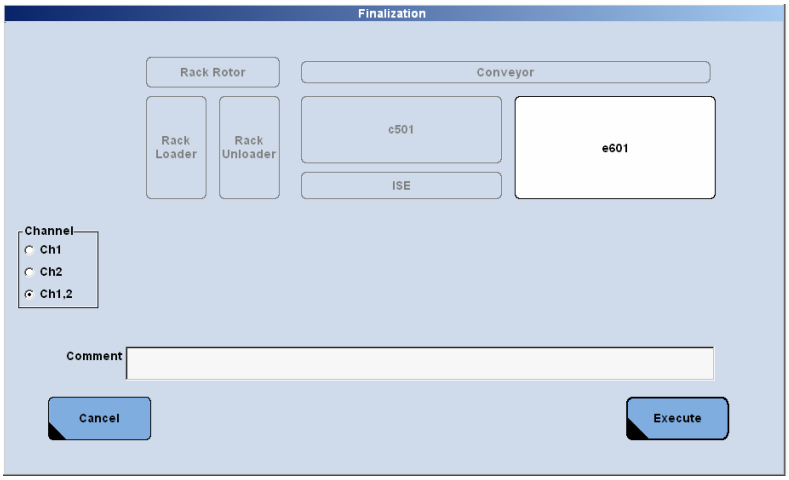


Figure E-280 Finalization window

Use this window to initiate the **Finalization** routine for the **e** 601 and desired measuring channel. Selected modules are highlighted white.

e 601 (5:30): Finalization routine is carried out on sample pipetter, reagent pipetter, sipper and detection unit.

Channel area

Use this area to specify a measuring channel.

Ch1 Select this option for measuring channel 1.

Ch2 Select this option for measuring channel 2.

Ch1, 2 Select this option for both measuring channels.

Comment The comment entered in this window will be printed on the maintenance report.

Empty PC/CC Reservoir window

➔ **Utility** > **Maintenance** > **Maintenance** (**Maintenance Type**) > **(33) Empty PC/CC Reservoir** > **Select**

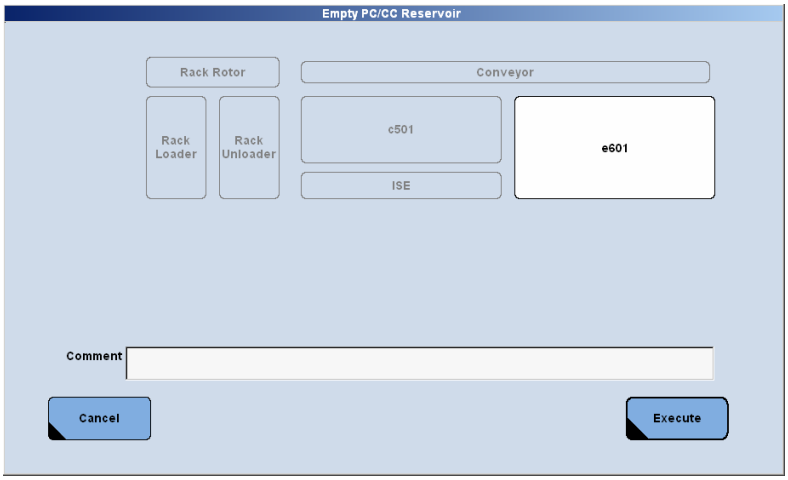


Figure E-281 Empty PC/CC Reservoir window

Use this window to initiate an **Empty PC/CC Reservoir** procedure on the **e** 601. Selected modules are highlighted in white.

e 601 (2:40): The liquid in the ProCell and CleanCell reservoirs is drained.

Comment The comment entered in this window will be printed on the maintenance report.

Initial Bead Mixing window

➔ **Utility** > **Maintenance** > **Maintenance** (**Maintenance Type**) > **(34) Initial Bead Mixing** > **Select**

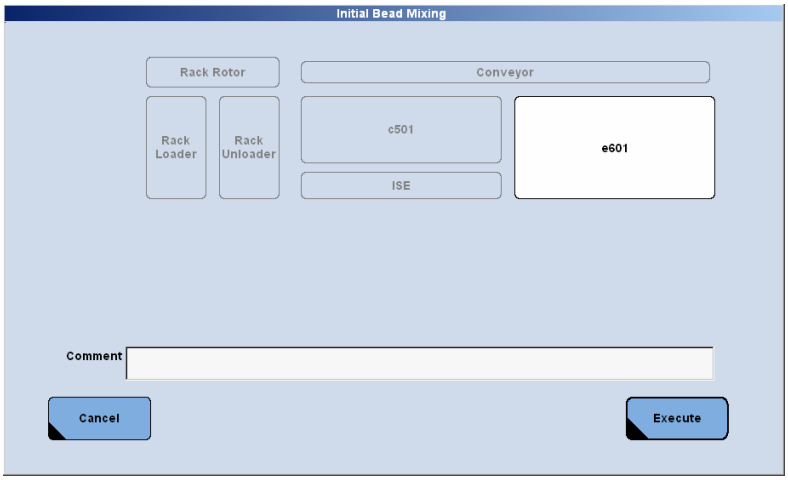


Figure E-282 Initial Bead Mixing window

Use this window to perform an **Initial Bead Mixing** on the **e** 601. Selected modules are highlighted in white.

e 601: Microbeads are mixed in all occupied positions on the reagent rotor.

Comment The comment entered in this window will be printed on the maintenance report.

Reagent Capping window

➔ **Utility** > **Maintenance** > **Maintenance** (**Maintenance Type**) > **(35) Reagent Capping** > **Select**

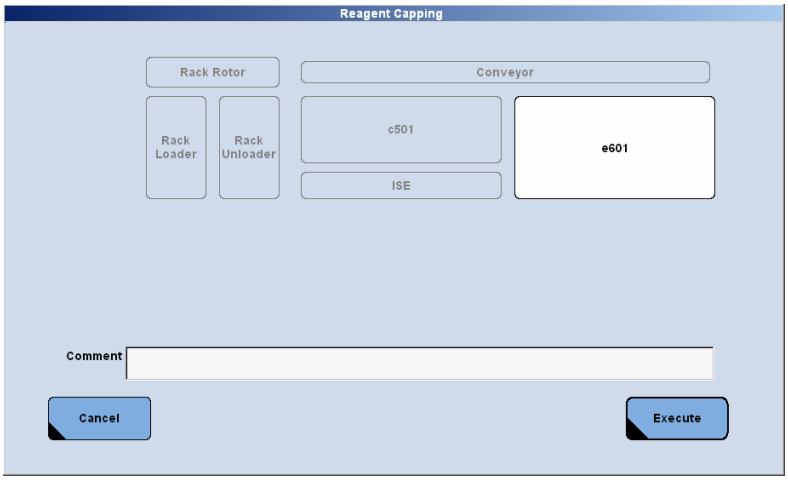


Figure E-283 Reagent Capping window

Use this window to initiate a **Reagent Capping** on the **e** 601. Selected modules are highlighted in white.

e 601: All open cobas e packs on the reagent rotor are closed.

Comment The comment entered in this window will be printed on the maintenance report.

AssayCup Discarding window

➔ **Utility** > **Maintenance** > **Maintenance** (**Maintenance Type**) > **(36) AssayCup Discarding** > **Select**

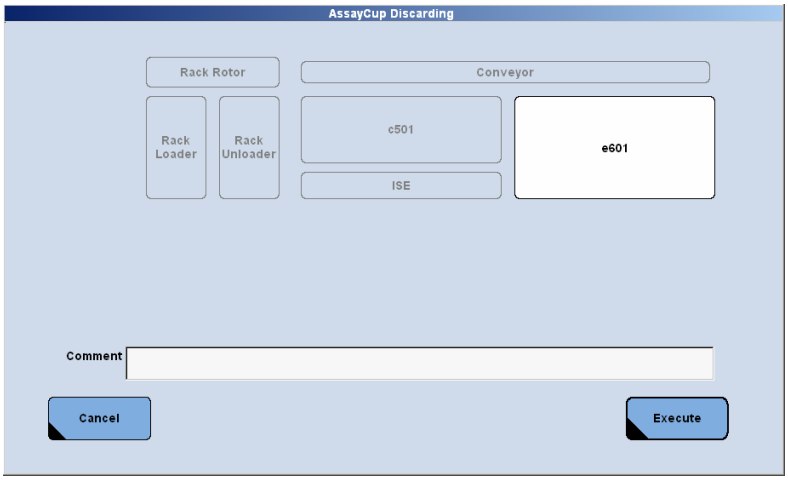


Figure E-284 AssayCup Discarding window

Use this window to initiate an **AssayCup Discarding** procedure on the **e** 601. Selected modules are highlighted in white.

e 601: All AssayCups are taken out of the incubator and discharged to the waste by the gripper.

Comment The comment entered in this window will be printed on the maintenance report.

System Air Purge (E Module) window

➔ **Utility** > **Maintenance** > **Maintenance** (**Maintenance Type**) > **(37) System Air Purge (E Module)** > **Select**

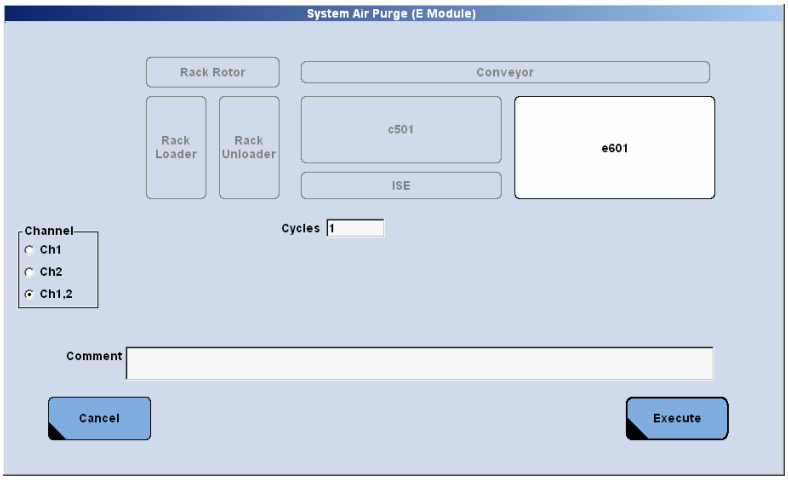


Figure E-285 System Air Purge (E module) window

Use this window to initiate a **System Air Purge** (**e** 601) on the **e** 601 and desired measuring channel. Selected modules are highlighted in white.

e 601: The following maintenance functions are performed:

(23) Pipetter Air Purge

(24) Sipper Air Purge

(31) Pre-wash Sipper Air Purge.

Channel area

Use this area to specify a measuring channel.

Ch1 Select this option for measuring channel 1.

Ch2 Select this option for measuring channel 2.

Ch1, 2 Select this option for both measuring channels.

Cycles Use this text box to enter the number of cycles to be performed (1 to 9999).

Comment The comment entered in this window will be printed on the maintenance report.

System Prime (E Module) window

➔ **Utility** > **Maintenance** > **Maintenance** (**Maintenance Type**) > **(38) System Prime (E Module)** > **Select**

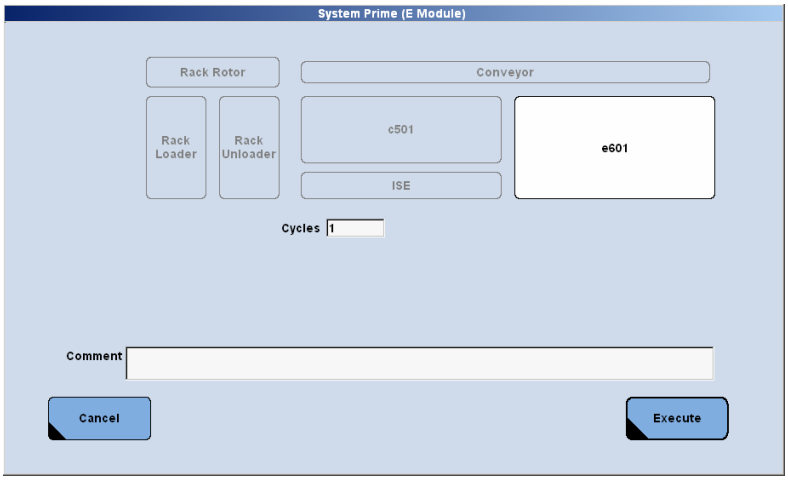


Figure E-286 System Prime (**e** 601) window

Use this window to initiate a **System Prime** on the **e** 601 and set the number of cycles. Selected modules are highlighted in white.

e 601: ProCell, CleanCell, and both Pre-wash lines are primed at the same time.

Cycles Use this text box to enter the number of wash cycles to be performed (1 to 9999).

Comment The comment entered in this window will be printed on the maintenance report.

Change Light Source Lamps window

➔ **Utility** > **Maintenance** > **Maintenance** (**Maintenance Type**) > **(39) Change Light Source Lamp** > **Select**

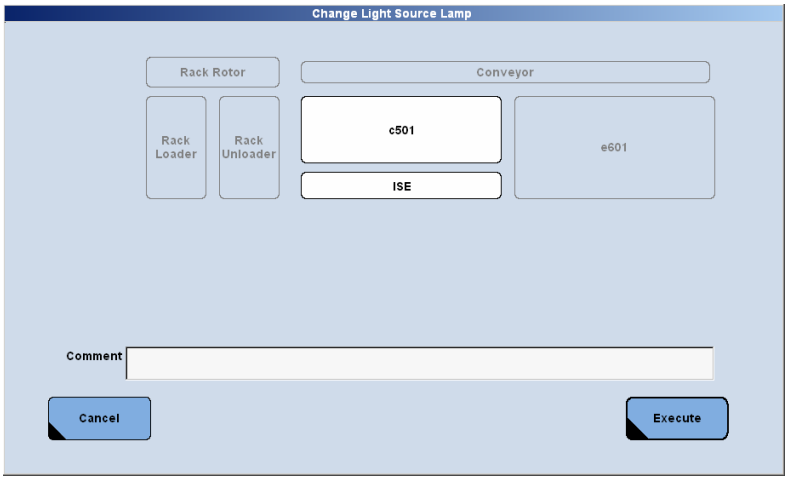


Figure E-287 Change Light Source Lamps window

Use this window to put the **c** 501 in *photometer lamp exchange* status. Selected modules are highlighted in white. Use this status whenever you replace a photometer lamp without switching off the analyzer.

c 501 (P): The photometer lamp is switched off. Use this item to exchange the photometer lamp without having to shut down the analyzer.

See *To remove the photometer lamp* on page C-103.

Comment The comment entered in this window will be printed on the maintenance report.

Trace Doc Export window

➔ **Utility** > **Maintenance** > **Maintenance** (**Maintenance Type**) > **(40) Trace Doc Export** > **Select**

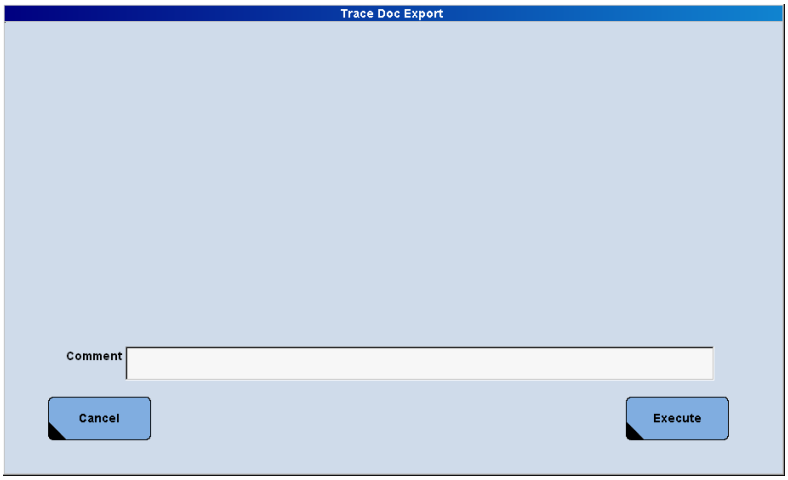


Figure E-288 Trace Doc Export window

c 501, e 601: Backup function; configuration settings and patient data (identical to Smart. Com Essential information upload) are exported from the flash memory of the analyzer to a selected storage medium. With software available from your Roche Diagnostics representative this file can be archived and viewed on external personal computers and provides traceability for test results.

It is recommended to perform this maintenance item every day, before any data has been deleted. It can be performed manually or in a maintenance pipe.

See *Data storage* on page B-244.

Comment The comment entered in this window will be printed on the maintenance report.

Maintenance checks

When **Check** is selected in the maintenance type list, the following maintenance checks are available in the maintenance item list for selection.

Maintenance item	Page	Maintenance item	Page
1 Check Disk	E-466	10 Reagent Pipetting Check	E-476
2 ISE Check	E-468	11 Cap Opener Check	E-477
3 Mechanisms Check	E-469	12 Bead Mixer Check	E-478
4 Sample Barcode Reader Check	E-470	13 Gripper Check	E-479
5 Reagent Barcode Reader Check	E-471	14 Magazine Exchange Check	E-480
6 Cassette Loading Check	E-472	15 Sipper Check	E-481
7 Cuvette Mixing	E-473	16 Pre-wash Probe Check	E-482
8 Reagent Short Sensor Check	E-474	17 Pre-wash Gripper Check	E-483
9 Sample Pipetting Check	E-475		

Table E-30 Maintenance check list

Check Disk window

➔ **Utility** > **Maintenance** > **Check** (**Maintenance Type**) > **(1) Check Disk** > **Select**

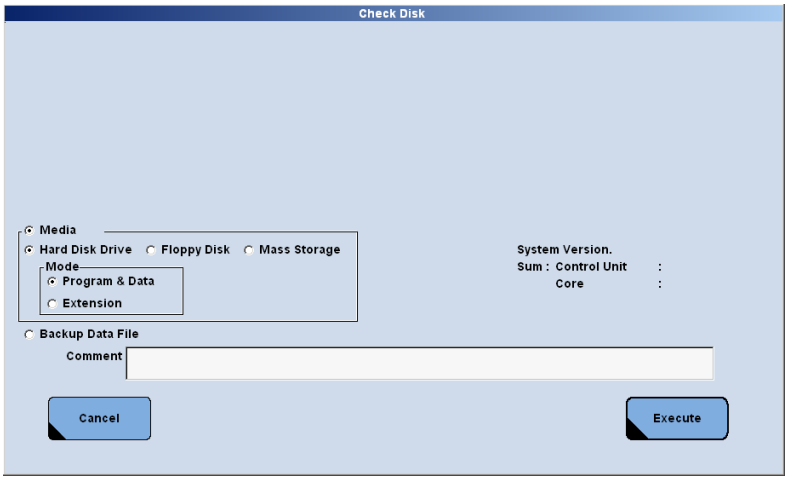


Figure E-289 Check Disk window

Use this window to initiate a disk check on a selected data carrier.

Files on hard disk, floppy disk, USB storage device, or DVD disk are checked by the control unit. A result list is available in the print buffer afterwards. This list is not automatically printed. The disk check can also be used to save a log file (Backup data file) and to determine the software version.

- The system must be in standby to perform a disk check.
- You cannot perform any other tasks on the system until the disk check is complete.
- Choose **Print** (global button) > **View** to display or print the directory listing in the print buffer.

Media area

Hard Disk Drive Select this option to check the files of the hard disk drive.

Floppy Disk Select this option to check the files of the floppy disk drive.

Mass Storage Select this option to check files of a mass storage.

If a USB storage device is inserted, the instrument uses the **USB** as mass storage.

If no USB storage device is inserted, the instrument uses a DVD disk as mass storage.

Mode area

Use the Mode area to select the mode of the disk check.

Program and Data Select **Program and Data** to check the programs and data on the database.

Extension Select **Extension** to check the file name extensions on the database.

Backup Data File

Backup Data File Select this option in order to gather instrument specific data for further investigation by the manufacturer. The analyzer writes instrument information into a log file on the database.

For more information about the **Backup Data File** function contact your Roche service representative.

To perform this function, a remaining capacity of at least 1 GB on the database is required.

Software information

The information displayed on the right side of the screen may be necessary when contacting your Roche service representative.

System Version The version of the software installed on the analyzer is displayed here.

Sum (Control Unit, Core) The check sum of the control unit software and the core software is displayed here.

Comment The comment entered in this window will be printed on the maintenance report.

ISE Check window

➔ **Utility** > **Maintenance** > **Check** (**Maintenance Type**) > **(2) ISE Check** > **Select**

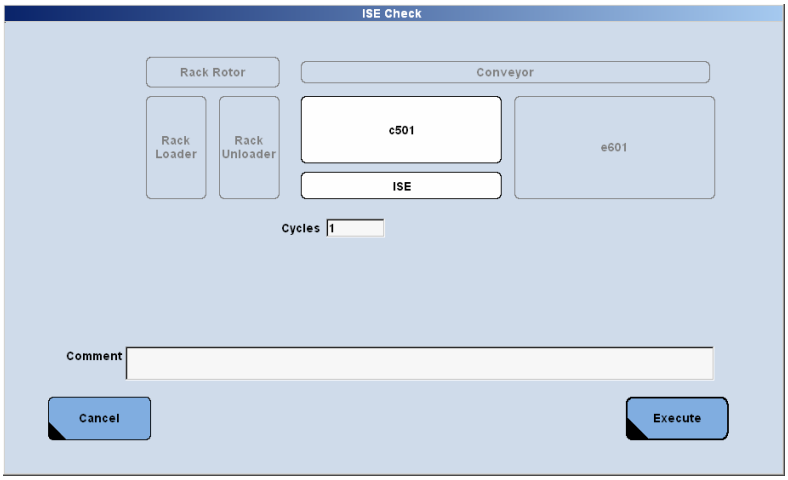


Figure E-290 ISE Check window

Use this window to initiate an **ISE Check** on the **c** 501 (ISE) and set the number of cycles. Selected modules are highlighted in white.

c 501(ISE): The electrode output of ISE cartridges ($Cl^-/K^+/Na^+$ and ISE reference cartridge) is measured with ISE IS and a listing of EMF values is printed out.

Cycles Use this text box to enter the number of cycles to be performed.

Comment The comment entered in this window will be printed on the maintenance report.

Mechanism Check window

➔ **Utility** > **Maintenance** > **Check** (**Maintenance Type**) > **(3) Mechanism Check** > **Select**

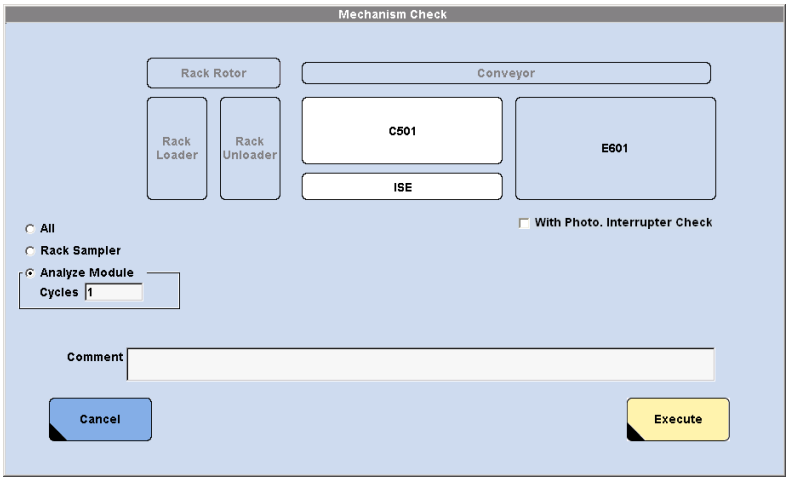


Figure E-291 Mechanism Check window

Use this window to initiate a **Mechanism Check** on the module(s). Selected modules are highlighted in white.

This maintenance check is used to check the functionality of all mechanical units on the main and rerun line and on the modules. If a malfunction occurs, the system issues an alarm. You may be instructed to perform a mechanisms check during troubleshooting of various instrument alarms.

All The option All performs a functional check of mechanical parts of the entire sample line and each module. Make sure to place some racks in the rack loader.

Rack Sampler The option Rack Sampler performs a functional check of mechanical parts of the rack sampler unit. Make sure to place some racks in the rack loader.

Analyze Module The option Analyze Module performs a mechanical check for selected modules according to entered number of cycles.

Cycles Use this text box to enter the number of cycles to be performed.

With Photo. Interrupter Check If the check box With Photo Interrupter check is selected, the system checks automatically all relevant photo coupler sensors during this maintenance function. Only the defective sensors are shown in the print view screen.

Choose **S. Stop** or **Stop** to end this option. The **S. Stop** button stops the continuous loop and automatically transports the racks to the unloader. The **Stop** button stops the racks immediately at whatever position they are in when **Stop** is chosen. A manual rack reset must be performed from the **Utility** > **Maintenance** in order for the racks to proceed to the unloader.

Comment The comment entered in this window will be printed on the maintenance report.

Sample Barcode Reader Check window

➔ **Utility** > **Maintenance** > **Check** (**Maintenance Type**) > **(4) Sample Barcode Reader Check** > **Select**

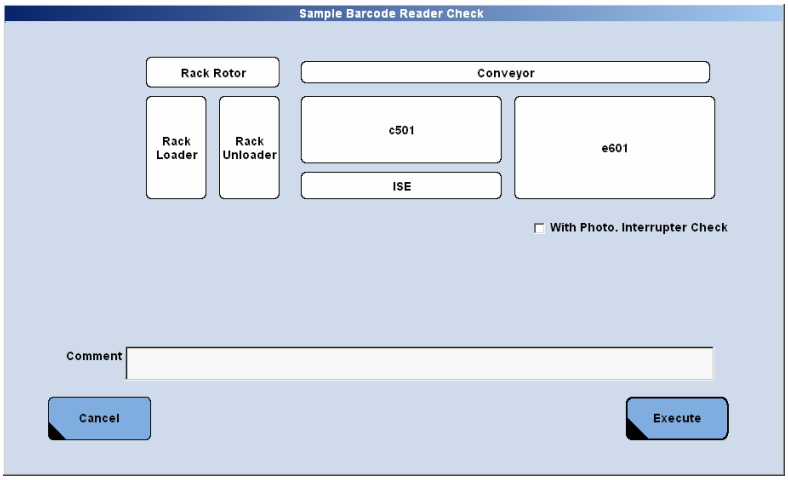


Figure E-292 Sample Barcode Reader Check window

Use this window to initiate a **Sample Barcode Reader Check** on the module(s).

The barcode on a sample tube is scanned. After pressing Stop, the data is displayed in the print preview for verification. There is no automatic printout. After pressing Stop a system reset has to be performed.

Set a rack with barcoded tubes in the rack loader and start the sample barcode reader check.

The rack moves first to the barcode reader in the rack feeder line. After reading the relevant positions the rack moves to the barcode reader in the sampling line of the selected modules.

According to the selected cycles the rack moves to the unloader or back to the rack feeder line.

The reading results are shown in the print view screen.

With Photo. Interrupter Check If the check box With Photo Interrupter check is selected, the system checks automatically all relevant photo coupler sensors during this maintenance function. Only the defective sensors are shown in the print view screen.

Comment The comment entered in this window will be printed on the maintenance report.

Reagent Barcode Reader Check window

➔ **Utility** > **Maintenance** > **Check** (**Maintenance Type**) > **(5) Reagent Barcode Reader Check** > **Select**

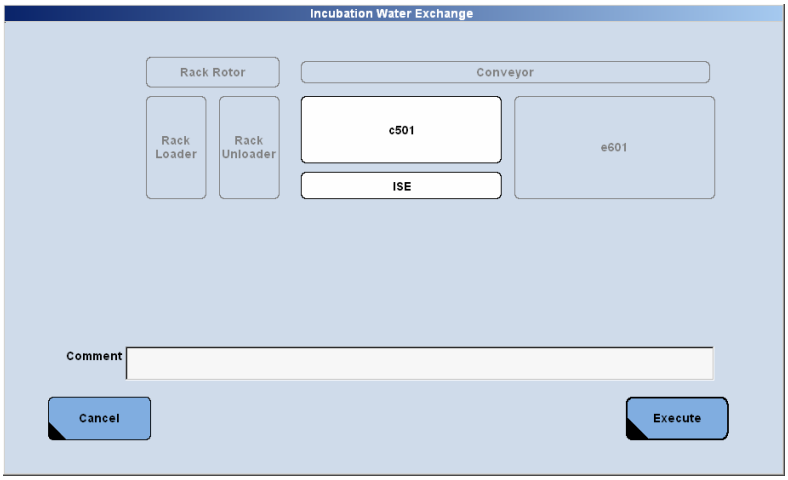


Figure E-293 Reagent Barcode Reader Check window

Use this window to initiate a **Reagent Barcode Reader Check** on the selected module(s).

The reagent barcode reader is checked according to input cycle (minimum is 5 cycles).

c 501: After starting the Reagent Barcode Reader Check a reagent cassette must be inserted in the cassette loading port. The gripper retracts the cassette automatically and the barcode reader reads in the barcode information on the cassette 5 times. Finally the results are shown in the print view screen. The cassette is ejected to the loading port and can be removed.

e 601: The barcodes of the loaded cobas e packs are read.

With Photo. Interrupter Check If the check box With Photo Interrupter check is selected, the system checks automatically all relevant photo coupler sensors during this maintenance function. Only the defective sensors are shown in the print view screen.

Cycles Use this text box to enter the number of cycles to be performed.

Cassette Loading Check window

➔ **Utility** > **Maintenance** > **Check** (**Maintenance Type**) > **(6) Cassette Loading Check** > **Select**

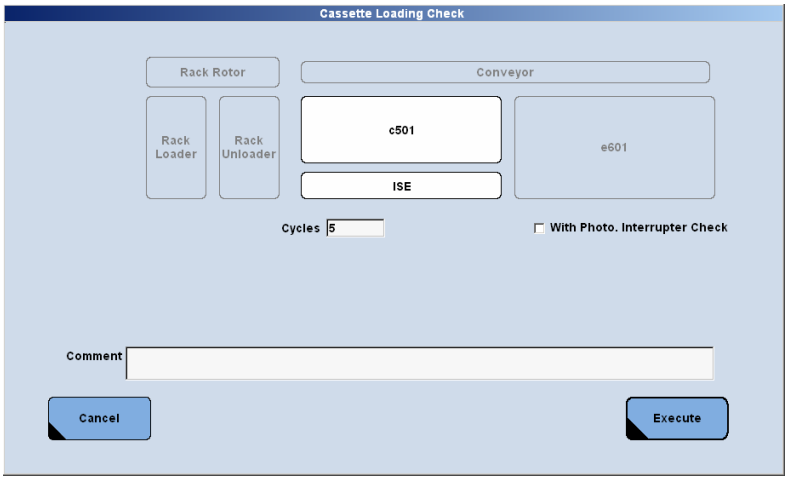


Figure E-294 Cassette Loading Check window

Use this window to initiate a **Cassette Loading Check** on the **c** 501.

c 501: A check for cassette loading, gripper and piercer movement is performed according to input cycle (minimum: 5 cycles).

With Photo. Interrupter Check If the check box With Photo Interrupter check is selected, the system checks automatically all relevant photo coupler sensors during this maintenance function. Only the defective sensors are shown in the print view screen.

Comment The comment entered in this window will be printed on the maintenance report.

Cuvette Mixing window

➔ **Utility** > **Maintenance** > **Check** (**Maintenance Type**) > **(7) Cuvette Mixing** > **Select**

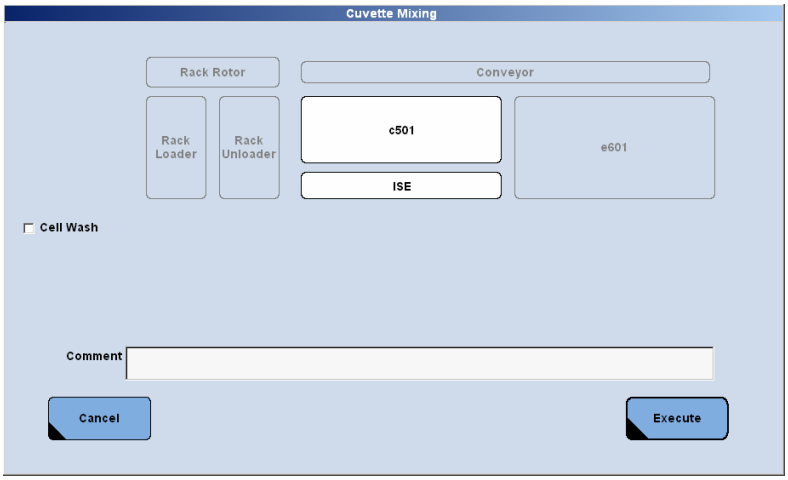


Figure E-295 Cuvette Mixing window

Use this window to initiate a check of the ultrasonic mixers on the **c** 501.

c 501: Performs a functional check on the ultrasonic mixers (1:32)—optionally with cell wash (system time with cell wash: 19:26).

The reagent probe pipettes deionized water in the corresponding cell (cuvette) for R1, R2 and R3 mixer. Then the cuvette turns to the mixing position and ultra sonic mixing is executed. The proper operation of the corresponding mixer can be checked visually—the water in the cuvette is vibrating when the mixer is operating.

Cell Wash Use this check box to perform Cell Wash prior to the actual intensity check.

See *To check the intensity of the ultrasonic output* on page C-100.

Comment The comment entered in this window will be printed on the maintenance report.

Reagent Short Sensor Check window

➔ **Utility** > **Maintenance** > **Check** (**Maintenance Type**) > **(8) Reagent Short Sensor Check** > **Select**

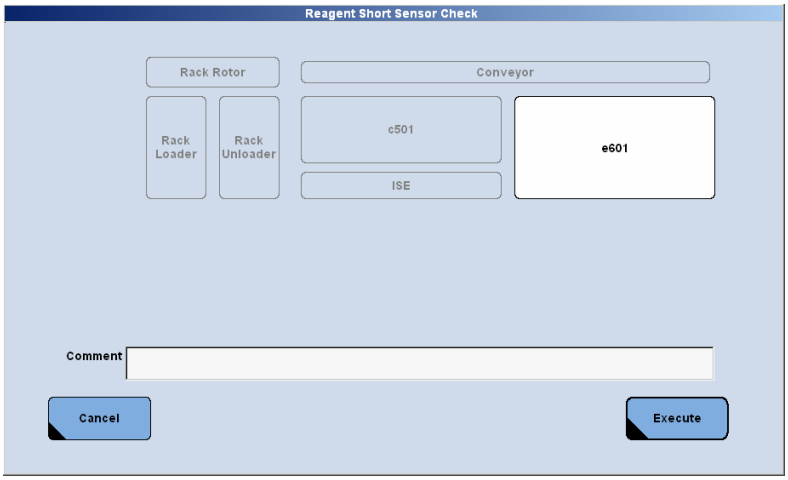


Figure E-296 Reagent Short Sensor Check window

Use this window to initiate a **Reagent Short Sensor Check** on the **e** 601.

e 601: The sensors in the lines of the PreClean, ProCell and CleanCell bottles will be checked.

Comment The comment entered in this window will be printed on the maintenance report.

Sample Pipetting Check window

➔ **Utility** > **Maintenance** > **Check** (**Maintenance Type**) > **(9) Sample Pipetting Check** > **Select**

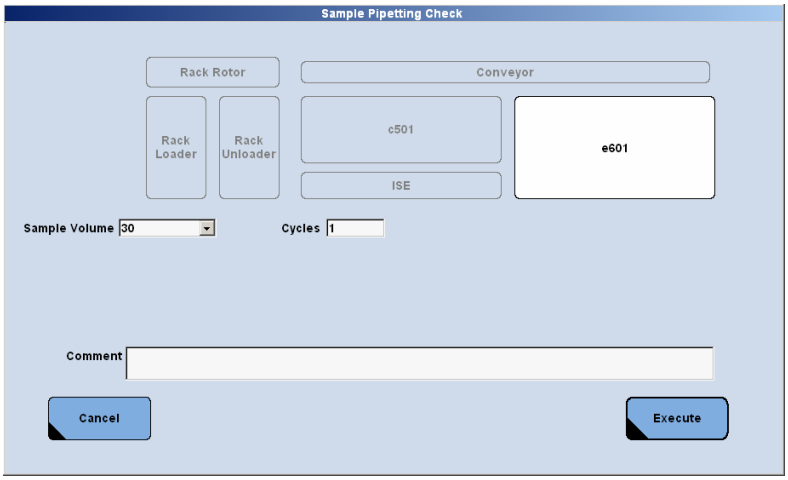


Figure E-297 Sample Pipetting Check window

Use this window to initiate a **Sample Pipetting Check** on the selected **e** 601 and set the number of cycles. Selected modules are highlighted in white.

e 601: The movement of the sample pipetter is checked and its liquid level detection function.

Sample Volume Use this list box to select the volume of the sample. Volumes from 10 to 50 µL can be selected in increments of 5 µL.

Cycles Use this check box to enter the number of cycles the check is to be performed (1 to 9999).

Comment The comment entered in this window will be printed on the maintenance report.

Reagent Pipetting Check window

➔ **Utility** > **Maintenance** > **Check** (**Maintenance Type**) > **(10) Reagent Pipetting Check** > **Select**

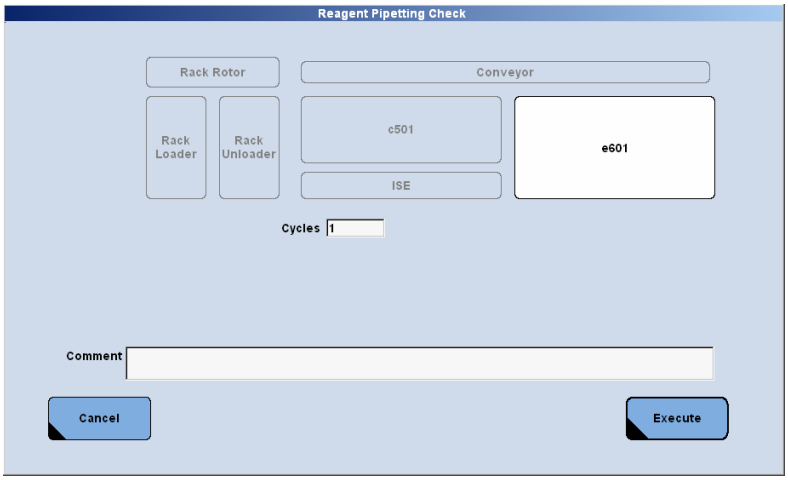


Figure E-298 Reagent Pipetting Check window

Use this window to initiate a **Reagent Pipetting Check** on the **e** 601 and set the number of cycles. Selected modules are highlighted in white.

e 601: The movement of the reagent pipetters is checked.

Cycles Use this check box to enter the number of cycles the check is to be performed (1 to 9999).

Comment The comment entered in this window will be printed on the maintenance report.

Cap Opener Check window

➔ **Utility** > **Maintenance** > **Check** (**Maintenance Type**) > **(11) Cap Opener Check** > **Select**

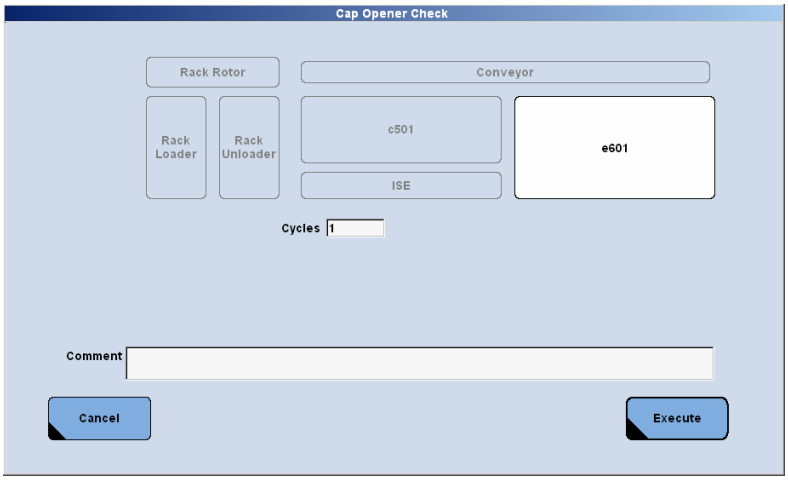


Figure E-299 Cap Opener Check window

Use this window to initiate a **Cap Opener Check** on the **e** 601 and set the number of cycles. Selected modules are highlighted in white.

e 601: The movement of the cap opener is checked.

Cycles Use this check box to enter the number of cycles the check is to be performed (1 to 9999).

Bead Mixer Check window

➔ **Utility** > **Maintenance** > **Check** (**Maintenance Type**) > **(12) Bead Mixer Check** > **Select**

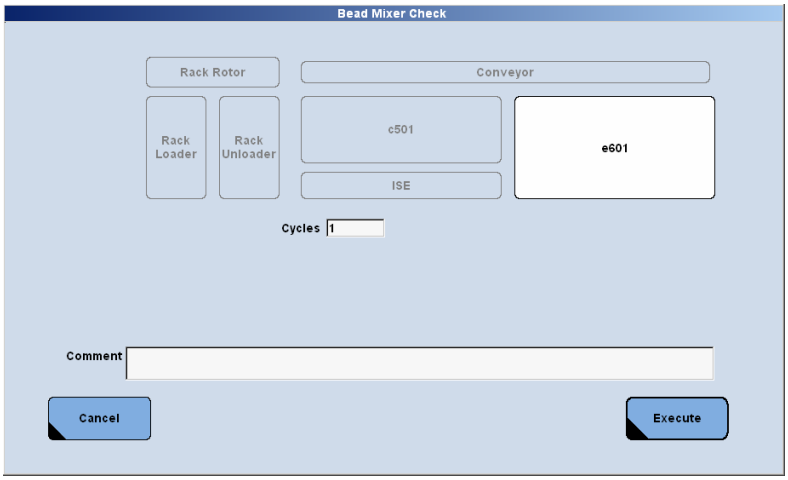


Figure E-300 Bead Mixer Check window

Use this window to initiate a **Bead Mixer Check** on the **e** 601 and set the number of cycles. Selected modules are highlighted in white.

e 601: The movement of the microbead mixer is checked.

Cycles Use this check box to enter the number of cycles the check is to be performed (1 to 9999).

Comment The comment entered in this window will be printed on the maintenance report.

Gripper Check window

➔ **Utility** > **Maintenance** > **Check** (**Maintenance Type**) > **(13) Gripper Check** > **Select**

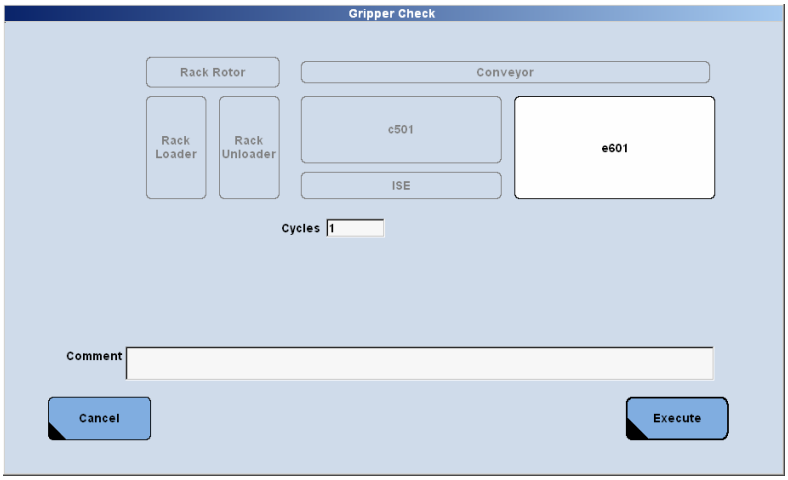


Figure E-301 Gripper Check window

Use this window to initiate a **Gripper Check** on the **e** 601 and set the number of cycles. Selected modules are highlighted in white.

e 601: The movement of the gripper and its tip and AssayCup handling function is checked.

Cycles Use this check box to enter the number of cycles the check is to be performed (1 to 9999).

Comment The comment entered in this window will be printed on the maintenance report.

Magazine Exchange Check window

➔ **Utility** > **Maintenance** > **Check** (**Maintenance Type**) > **(14) Magazine Exchange Check** > **Select**

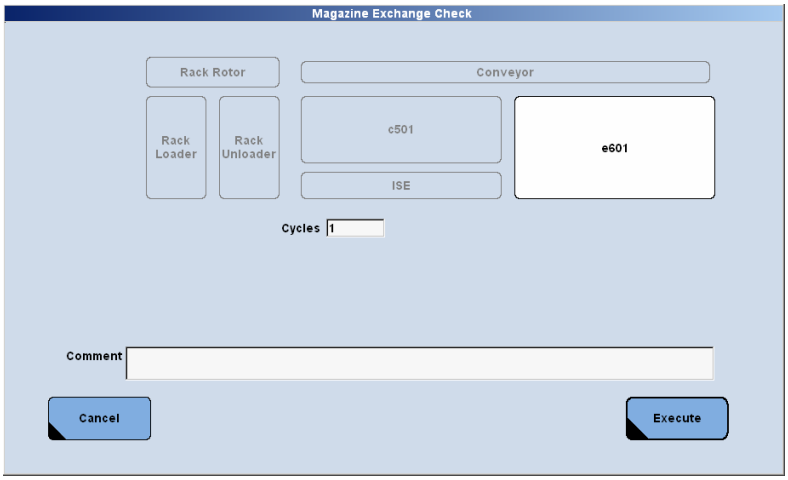


Figure E-302 Magazine Exchange Check window

Use this window to initiate an AssayTip/AssayCup **Magazine Exchange Check** on the **e** 601 and set the number of cycles. Selected modules are highlighted in white.

e 601: The movement of the magazine exchange is checked.

Cycles Use this check box to enter the number of cycles the check is to be performed (1 to 9999).

Comment The comment entered in this window will be printed on the maintenance report.

Sipper Check window

➔ **Utility** > **Maintenance** > **Check** (**Maintenance Type**) > **(15) Sipper Check** > **Select**

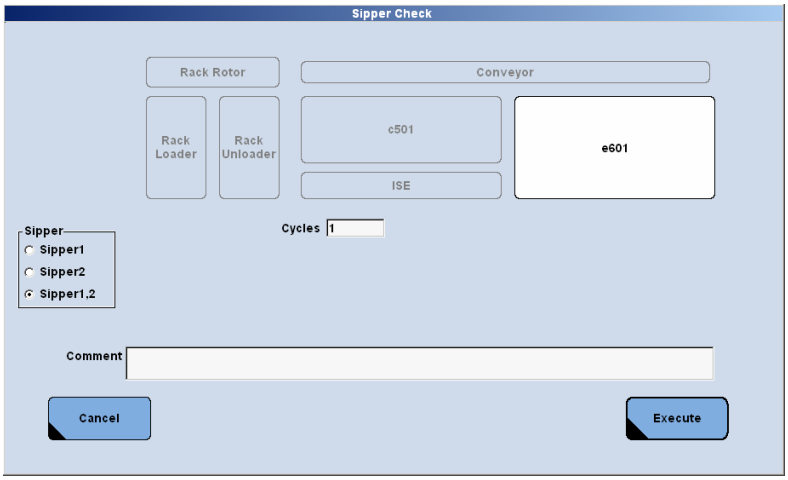


Figure E-303 Sipper Check window

Use this window to initiate a **Sipper Check** on the **e** 601 and set the number of cycles. Selected modules are highlighted in white.

e 601: The movement of the sippers and their liquid level detection function is checked.

Cycles Use this check box to enter the number of cycles the check is to be performed (1 to 9999).

Sipper area

Sipper1 Select the **Sipper1** option to check the sipper for measuring cell 1.

Sipper2 Select the **Sipper2** option to check the sipper for measuring cell 2.

Sipper1,2 Select the **Sipper1,2** option to check both sippers.

Comment The comment entered in this window will be printed on the maintenance report.

Pre-wash Probe Check window

➔ **Utility** > **Maintenance** > **Check** (**Maintenance Type**) > **(16) Pre-wash Probe Check** > **Select**

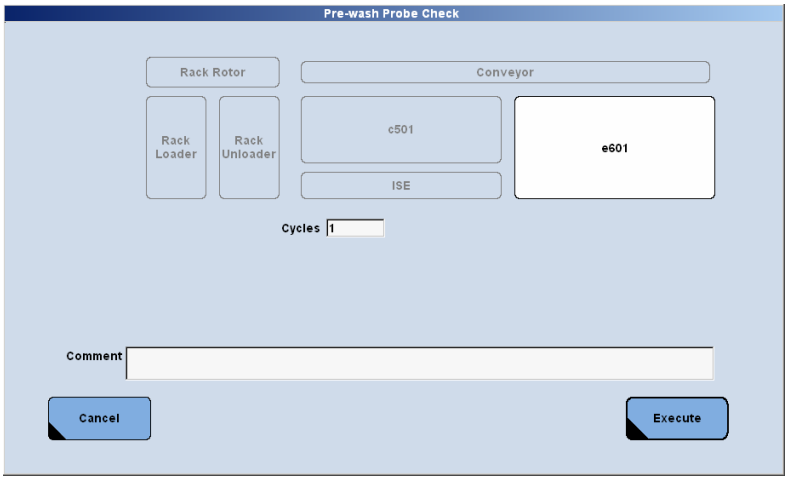


Figure E-304 Pre-wash Probe Check window

Use this window to initiate a **Pre-wash Probe Check** (sipper) on the **e** 601 and set the number of cycles. Selected modules are highlighted in white. Make sure to place AssayCups in the pipetting positions of the **Pre-wash** area.

e 601: The movement and function of the Pre-wash sipper is checked. The Pre-wash sipper and syringe will aspirate and discharge PreClean during this procedure.

Manually add cups to the separation stations.

Cycles Use this check box to enter the number of cycles the check is to be performed (1 to 9999).

Comment The comment entered in this window will be printed on the maintenance report.

Pre-wash Gripper Check window

➔ **Utility** > **Maintenance** > **Check** (**Maintenance Type**) > **(17) Pre-wash Gripper Check** > **Select**

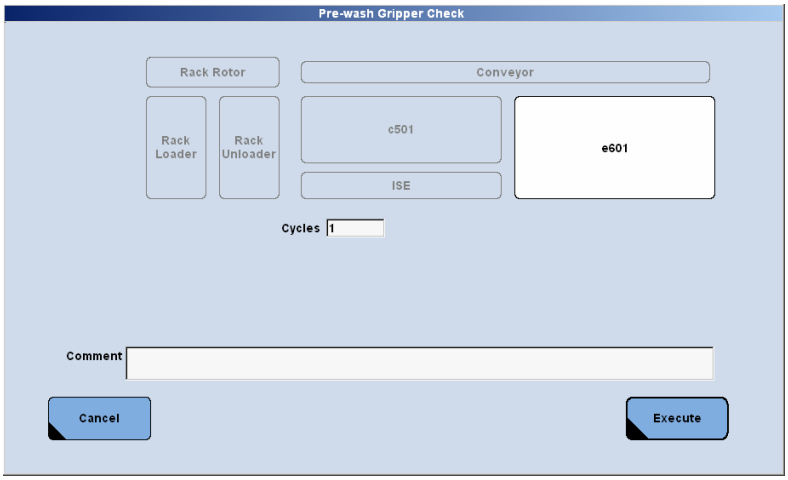


Figure E-305 Pre-wash Gripper Check window

Use this window to initiate a **Pre-wash Gripper Check** on the **e** 601 and set the number of cycles. Selected modules are highlighted in white.

e 601: The movement of the Pre-wash Gripper is checked as well as its AssayCup handling function.

Make sure to place AssayCups on the following positions before you start this procedure:

- Pre-wash Gripper position on the incubator (position 6)
- Vortex mixer position
- First position in the Pre-wash station

Cycles Use this check box to enter the number of cycles the check is to be performed (1 to 9999).

Comment The comment entered in this window will be printed on the maintenance report.

Application screen

➔ **Utility** > **Application**

This screen can be viewed by an operator with a supervisor level, but an administrator level or higher is required to edit the data.

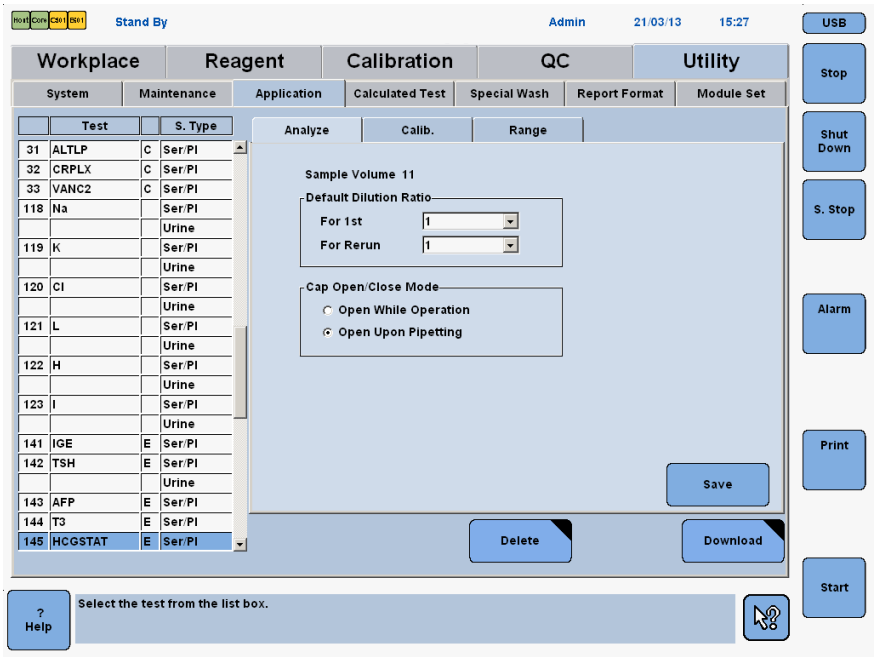


Figure E-306 Application screen

This screen is used to update or change application parameters.

Test list

This list displays all tests programmed on the system with the corresponding analytical module and sample type and the test number. A total of 191 applications may be active in the system at any time. The following table shows the allocation of the test numbers.

Number	Type of Test
1-117	Clinical chemistry
118-120	Electrolytes (sodium, potassium, chloride)
121-123	Serum indexes (lipemic, hemolysis, and icterus)
	8 calculated tests without test numbers
141-200	Immunological tests

Table E-31 Allocation of test numbers

No. The **No.** column displays the test number according to the download order from **cobas** link to the system.

Test The **Test** column displays the test name as specified in the download screen.

Module The **Module** column displays the module to which this test belongs.

S. Type The **S. Type** column displays the sample type for which the test is specified.

Analyze Choose the **Analyze** tab to display analysis parameters for each application. This tab is not available for electrolyte tests.

For more information, see:
Analyze (c 501, photometric tests) on page E-486
Analyze (serum indexes) on page E-490
Analyze (e 601 tests) on page E-492

Calib. Choose the **Calib.** tab to display calibration settings. This tab is not available for serum indexes.

For more information, see:
Calib. (c 501 (ISE) tests) on page E-494
Calib. (photometric tests) on page E-496
Calib. (e 601 tests) on page E-500

Range Choose the **Range** tab to display the application code, printed test name, test priority, control intervals, repeat limit and expected value ranges. This tab is not available for serum indexes.

For more information, see:
Range (c 501 ISE and photometric tests) on page E-503
Range (e 601 tests) on page E-507

Other Choose the **Other** tab to display the **Other** tab used to display calibrator codes and settings. This tab is not available for either serum indexes or immunological tests.

For more information, see:
Other (c 501 ISE tests) on page E-510
Other (c 501 photometric tests) on page E-512

Delete Use this button to remove the application selected in the **Test** list from the system after confirmation.

If an application is deleted from the system, corresponding calibrators (**c** 501 only) and controls data will also be deleted.

Download Use this button to download new test application parameters from **cobas** link.

Analyze (c 501, photometric tests)

➔ **Utility** > **Application** > **Analyze**

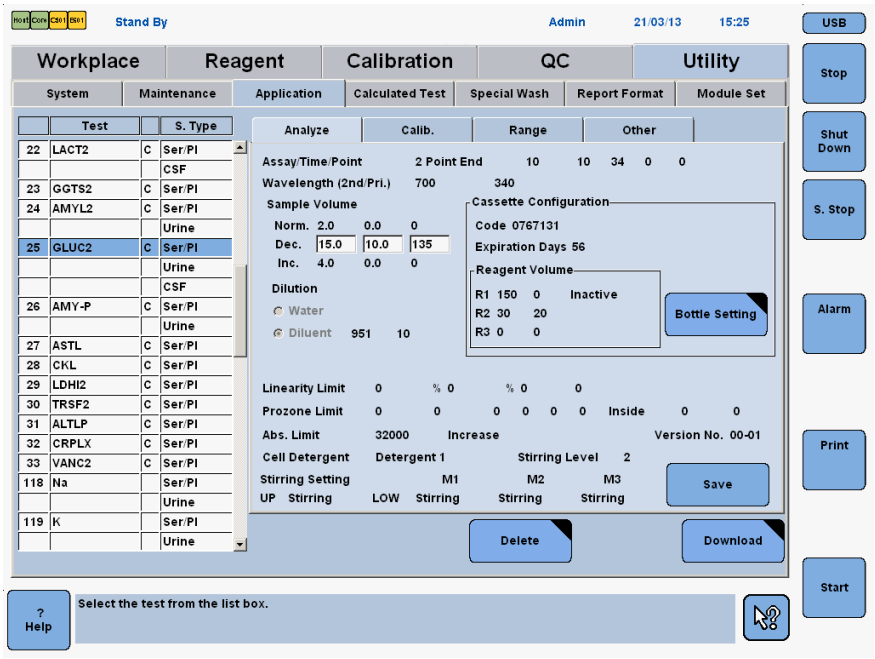


Figure E-307 Analyze tab (photometric test on **c** 501)

Use this screen to display analysis parameters for each test. These parameters include assay time and measuring points, wavelengths, sample volumes, diluents, reagent volumes and reagent refresh intervals, absorbance limits, prozone limits and cell detergent. Serum index interference values are also displayed in this window.

Only values with a white background can be edited.

For information on the **Test** list and **Delete** and **Download** buttons, see *Test list* on page E-484.

For more information, see:
Downloading new application parameters on page B-255
Description of application parameters on page B-260

Assay/Time/Point The **Assay/Time/Point** line contains six fields:

Assay type This text box displays the assay type (1 Point, 2 Point Rate, 2 Point End, 3 Point, 1 Point Rate, Rate A, Rate B).

Reaction time This test box displays the reaction time for the selected application. The reaction times are in minutes.

Measuring point

This text boxes displays the measuring points used in the calculation for the assay type selected in assay type text box. The following values are possible:

- 1 to 73, excluding 26, 27, 65 and 66
- A value of "0" indicates no further measuring point

Wavelength (2nd/Primary)

These 2 text boxes display the secondary and primary wavelengths in nanometers. The first box displays the secondary wavelength. The second box displays the primary wavelength. Possible values are 340, 376, 415, 450, 480, 505, 546, 570, 600, 660, 700, and 800.

Sample Volume area

This area displays sample volumes for normal, decreased and increased samples. The dilution volumes are also displayed.

Normal/Decrease/Increase Field 1

Sample Volume: The first text box displays the sample volume in microliters used for analysis or used for dilution.



If the sample volume of a test is higher than 20 µL, a manual requested dilution on **Workplace** > **Test Selection** is not accepted and a pop-up window is displayed.

Normal/Decrease/Increase Field 2

Diluted S. Volume (Diluted sample volume): The second text box displays the sample volume taken for analysis from the diluted sample in microliters. A value of 0 indicates no dilution. This volume is specified for normal, decreased, and increased sample volumes.

Normal/Decrease/Increase Field 3

Diluent Volume: This text box displays the diluent volume in microliters (20.0 to 270.0 µL) used for dilution of the sample in the reaction cell. A value of 0 indicated no dilution. This volume is specified for normal, decreased, and increased sample volumes.

Application screen

Dilution area

Water The **Water** option displays if water is chosen as the diluent for this application.

Diluent The **Diluent** option displays if diluent is chosen as the diluent for this application.

This text box displays the application code of the diluent.

This text box shows the dilution ratio for the diluent. For example a dilution ratio of 1:10 is displayed as *10*

Prozone Limit

The prozone check is used to detect a high dose hook effect in turbidimetric assays. A signal related to the right hand side of the dose response curve (Heidelberger Curve) can lead to a falsely low concentration result. Prozone limit check can also be used to detect unexpected reaction kinetics when measuring gammopathic samples.

Field 1-2 This box displays the prozone limit for the respective application. The value in this box is absorbance and lies between -32000 and 32000.

Fields 3 through 6 These boxes display the number of the assigned prozone measuring points. If **0** is displayed, then no prozone measuring point is set. A number from 1 to 70, excluding 26, 27, 65 and 66 is possible.

Field 7 This box displays whether the prozone check value should be **Inside** or **Outside** the limits defined in Field 1 and 2.

Field 8-9 These boxes display the minimum initial absorbance difference and minimum final absorbance difference. When the measured absorbance differences are lower than these values a prozone check will not be performed. An entry of "0" indicates no limits are given.

Miscellaneous fields

Linearity Limit In the rate assay, the relationship between the absorbance change and time must be linear. If the linearity is beyond the limit value, an alarm flag *lin.* is attached to the result.

1st entry field	Linearity Limit for Rate assays with 4-16 points	[0-100] (0: No Check)
2nd entry field	Linearity Limit for Rate assays with ≥ 17	[0-100] (0: No Check)
3rd entry field	Execution marginal value (Minimum total rate)	[0-32000]
4th entry field	Execution marginal value (Minimum margin rate)	

For more information about calculating the Linearity Limit, refer to the *COBI CD, Chapter 12, Linearity verification (NonLin).*

Abs. Limit These 2 boxes display the absorbance limit for a rate assay. The value in the first box is absorbance and lies between 0 and 32000. The word **Increase** in the second box indicates an increasing absorbance rate assay. The word **Decrease** in the second box indicates a decreasing absorbance rate assay.

Version This field displays the parameter version number.

*Cell Detergent (**c** 501* (P) *only)* This box displays which detergent (**Detergent 1**, **Detergent 2**, or **Detergent 1 & 2**) is used for rinsing the reaction cell after the measurement on the **c** 501 (P).

Stirring level The stirring level is a fixed parameter of the test application.

Range: [1-15]

Stirring Setting During ultrasonic mixing in a reaction cell, tests in the cell next to the ultrasonic mixing can be disturbed. Therefore some reaction cells will be left out next to the ultrasonic mixing one.

Cassette Configuration area (c 501 (P))

Code This text box displays the cassette code for the reagent.

Expiration Days This text box displays the reagent working solution stability in days.

Reagent Volume On **c** 501 (P), each photometric test can have up to 2 different reagent additions occurring at different timing intervals. For each reagent addition 2 entries are shown: reagent volume and diluent volume. Each of these 2 entries is explained below.

R1 Field 1 … R3 Field 1 The first column displays the volume of reagent pipetted for concentrated reagent (0 for none).

R1 Field 2 … R3 Field 2 The second column displays the volume of diluent pipetted (0 for none).

R1 Field 3... R3 Field 3 The third column displays the dummy volume that is aspirated when pipetting reagent. **Inactive** means that no dummy volume is aspirated. The dummy volume setting is displayed for Reagent R1 only but it is also effective for reagents R2 and R3.

Bottle Setting Use this button to open the **Bottle Setting** window and specify reagent bottle settings.

See *Bottle Setting window* on page E-417.

Analyze (serum indexes)

➔ **Utility** > **Application** > serum index test (121-123 on **Test** list)

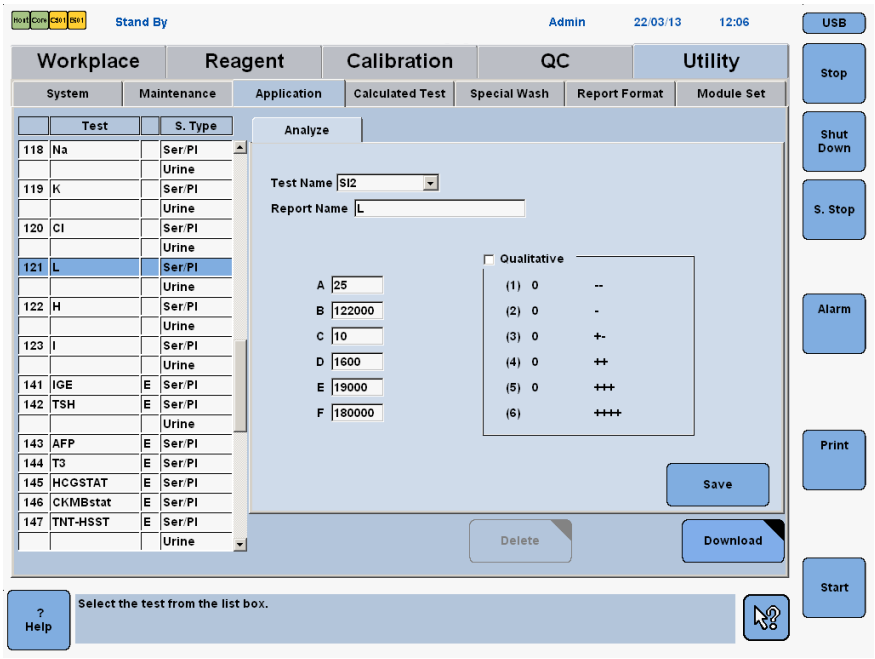


Figure E-308 Analyze tab (Serum Indexes)

Use this screen to specify analysis parameters for serum indexes.

👁 For information on the **Test** list and **Delete** and **Download** buttons, see *Test list* on page E-484.

Test Name Use this list box to select the test SI2 for which the serum index measurement is carried out and press <Enter>. Selecting **Cancel** indicates no test is performed.

Report Name Use this text box to specify the name for the serum index calculation. This name appears in the patient report. Type the report name (up to 22 characters) and press <Enter>.

👁 For more information on serum indices, refer to the COBI CD.

Factor area

Use the text boxes in this area to define factors **A** through **F** for the calculation of the serum index. Type a factor (0 to 999999) in the appropriate text box and press <Enter>. Recommended values for each factor are as follows:

- A = 25 (conventional units) or 40 (international units)
- B = 122000 (conventional or international units)
- C = 10 (conventional or international units)
- D = 1600 (conventional units) or 94 (international units)
- E = 19000 (conventional or international units)
- F = 180000 (conventional or international units)

The factors are identical for hemolysis, icterus and lipemic. After combining any serum index parameter (H, I or L) with the test SI2, all other serum index parameters are combined with this test automatically.

Limits for H, I and L index are implemented in conventional units in all application settings. When using international units for H and I index the respective serum index limits have to be changed in all applications.

Please recalculate the H limit with the following factors:

H: Limit H (international units) = Limit H (conventional units) x 0.621

I: Limit I (international units) = Limit I (conventional units) x 17.1

Qualitative area

Select the check box to enable qualitative result reporting. If the check box is blank, qualitative result reporting is turned off. If selected, fields **(1)** through **(6)** are activated.

(1) through (5) Use the first text box to define the qualitative limit for range 1-5. This range does not appear on the patient report. Type the limit (-99999 to 999999) and press <Enter>. Any result less than or equal to the value defined here prints the text defined in the second text box.

Use the second text box to define the characters that print on the patient report. Up to 6 characters (such as --, ++, +-, ++++, etc.) can be entered. Type the desired characters and press <Enter>.

(6) Use this text box to define the characters that print on the patient report for results above the upper limit of range 5. Up to 6 characters (such as --, ++, +-, ++++, etc.) can be entered. Type the desired characters and press <Enter>.

Analyze (e 601 tests)

➔ **Utility** > **Application** > select **e** 601 test > **Analyze**

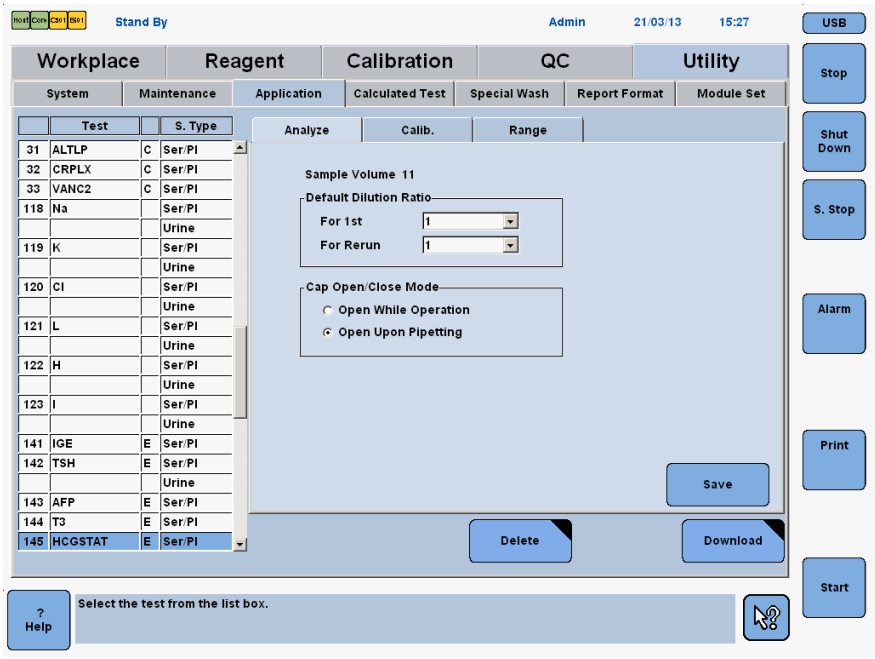


Figure E-309 Analyze tab (**e** 601)

Used this screen to display application parameters for **e** 601 applications.

For information on the **Test** list and **Delete** and **Download** buttons, see *Test list* on page E-484.

For more information, see:
Downloading new application parameters on page B-255
Description of application parameters – Analyze tab on page B-261
Dilution ratios (e 601) on page B-262

Sample Volume This text box displays the volume of sample required for the selected application.

Default Dilution Ratio area

Use this area to define the dilution ratio for the selected application.

For 1st Use this list box to select the desired dilution ratio for 1st test measurement. The value defined in the **For 1st** text box is used when **Normal** is selected for the **S.Vol./D.Ratio** on **Workplace** > **Test Selection**, or at the default profile measurement.

For Rerun Use this list box to select the desired dilution ratio for rerun test measurements. The value defined in the **For Rerun** text box is used for the rerun. In addition if **Decrease** is selected for the **S.Vol./D.Ratio** on **Workplace** > **Test Selection** this dilution ratio is automatically used.

Cap Open/Close Mode area

Use this area to define the reagent pack cap open/close mode for the application currently selected.

Open While Operation Select the **Open While Operation** option to keep the reagent pack cap open when the system is in Operation mode.

Open Upon Pipetting The **Open Upon Pipetting** option is the default setting after download. If this option is selected the reagent pack cap is opened only when the reagent is to be pipetted. This way the reagent pack lid remain closed when it is not in use and therefore evaporation effects are reduced.

Calib. (c 501 (ISE) tests)

➔ **Utility** > **Application** > ISE test (118-120 on **Test** list) > **Calib.**

Only values with a white background can be edited.

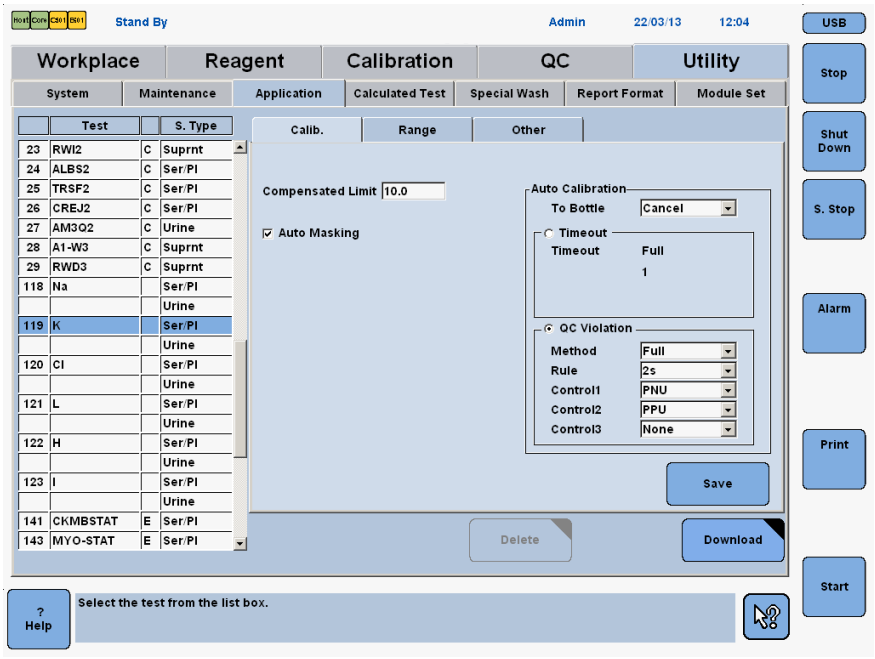


Figure E-310 Calib. tab (ISE tests)

Use this screen to display calibration parameters.

For information on the **Test** list and **Delete** and **Download** buttons, see *Test list* on page E-484.

Compensated Limit Use this text box to define the limit at which a *Cal.E* alarm will occur during calibration for ISEs. A calibration alarm occurs because either the slope or calibrator concentration differs by more than the specified percentage from previous calibrations and thus exceeds the compensated limit. Type the limit (0 to 200%) and press <Enter>.

Auto Masking Use this check box to activate or deactivate the auto masking function for the application currently selected. If this check box is checked, the application can be automatically masked when a calibration has failed or no valid calibration is available.

The **auto masking** function must be activated on the **Utility** > **System** (**Page 2/4**) > **Calib Mask Setting**. This is the main switch to turn on the **Calib Mask** function for the system.

See:
Calibration masking (auto masking) on page B-239
Calibration Mask Setting window on page E-392

Auto Calibration area This area contains the option **To Bottle** and two subareas: **Timeout** and **QC Violation**. **Timeout** and **QC Violation** are two mutually exclusive options:

Timeout: Choose this option to instruct the system to automatically recommend calibrations at regular intervals. All settings are made in the **Timeout** subarea.

QC Violation: Choose this option to instruct the system to issue QC-triggered calibration recommendations. All settings are made in the **QC Violation** subarea.

To Bottle Use this list box to select the method of bottle-to-bottle calibration. Selections available are **Cancel**, **Blank**, **2 Point** and **Full**. If **Cancel** is selected, an automatic calibration does not take place when a new bottle of reagent is used for the test.

Timeout

Choose this option to configure and use automatic calibration recommendations at regular intervals (Timeout calibrations). It is possible to work either with timeout calibration or QC violation calibration recommendations, however timeout is set by default.

Timeout Use this list box to select the method of automatic calibration recommendations at regular intervals. Selections available are **Cancel**, **Blank**, **2 Point** and **Full**. If **Cancel** is selected, no calibration recommendation at regular time intervals will be issued.

Use the text box to define the regular time interval for automatic calibration recommendations (number of days).

QC Violation

Choose this option to configure and use QC-triggered calibration recommendations.

Use the boxes in this area to set a confidence range and to preselect the calibration method to be recommended in case of a QC violation through the specified controls.

Method Use this box to select a calibration method (**Blank**, **Span**, **2 Point**, or **Full**). When the system recommends a calibration due to QC violation, it recommends the calibration method which is preselected here.

Rule Use this box to set the confidence range.

- **1s** denotes a range for acceptable QC results of QC target value ±1 SD, where SD is the application's standard deviation.
- **2s** denotes a range of QC target value ±2 SD.
- **3s** denotes a range of QC target value ±3 SD.

The actual values for the QC target value, SD, and the confidence limits are displayed on the **QC** > **Install** screen.

For more details on editing confidence limits, see *Editing control values* on page B-224.

Control Up to 3 different controls can be selected for each application. At least 1 control must be selected to get a valid configuration.

Choose the arrow in the control box(es) to open a list of available controls. This list shows all controls that supply target and SD values for the currently selected test. Select a control from the list.

Calib. (photometric tests)

➔ **Utility** > **Application** > photometric test (1-117 on **Test** list) > **Calib.**

If the field is grayed out, the field is read only for the password level logged onto the system. At an administrator level, if the field is not grayed out, it can be edited.

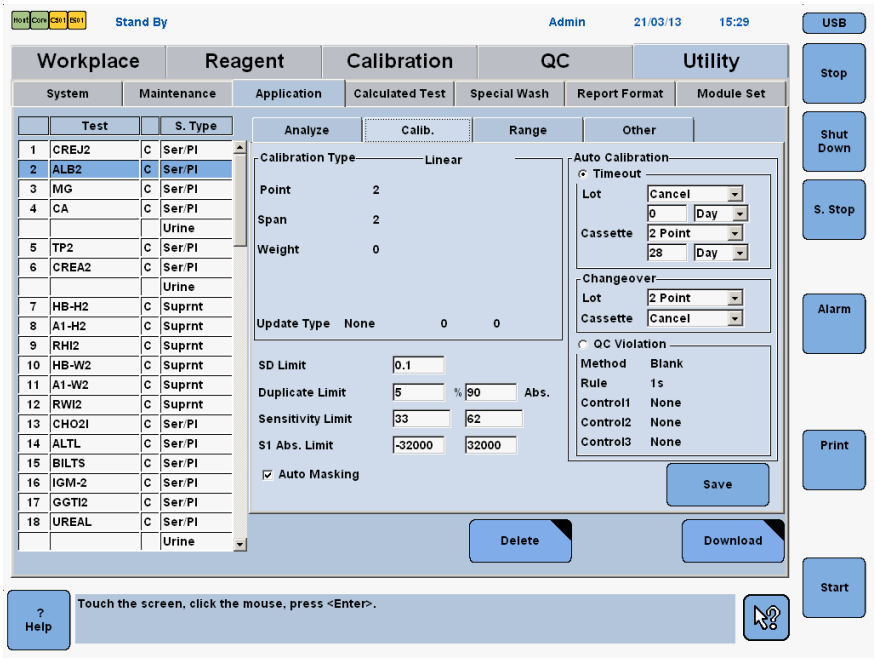


Figure E-311 Calib. tab (photometric test)

Use this screen to display calibration parameters. These parameters include calibration type parameters, parameters for calibration checks (**SD limit**, **duplicate limit**, **sensitivity limit**, **S1 Absorbance limit**), and parameters for automatic calibration recommendations. For Roche Diagnostics applications, these parameters are downloaded via **cobas** link.

For information on the **Test** list and **Delete** and **Download** buttons, see *Test list* on page E-484.

Calibration Type area

Calibration Type This box displays the calibration curve type of the selected test. Calibration types include: **Linear**, **Spline**, **Line Graph**, **RCM**, **RCM2T1**, and **RCM2T2**.

Point This text box displays the number of standards used for calibration.

Span This text box displays the span calibration point (standard measured in span calibration). If **0** is entered, the span calibrator is not defined.

Weight This text box displays the weight applied to the standard solution. Possible values are **0**, **1**, or **2**. If **0** is defined, no weighting will occur during the calibration.

Update Type The first box displays the type of calibration update. Possible values are **None**, **Difference**, or **Ratio**.

The next boxes display the numbers of the calibrators (1-6) used for calibration update.

For more information, refer to the COBI CD.

Calibration checks limits

SD Limit Use this text box to specify the standard deviation (SD) limit. When calibrating nonlinear or multipoint linear tests, the instrument compares the measured absorbance of each calibrator against its ideal absorbance and calculates SD.

If the calculated SD is not less than this SD limit, an SD.E alarm is issued. Type the SD limit from 0.1 to 999.9 and press <Enter>.

Duplicate Limit Use these 2 text boxes to define the limit for calibrator acceptability.

Type the % error limit (0 to 99%) in the first text box and press <Enter>. Type the duplicate limit for Abs error from 0 to 32000 in the second text box and press <Enter>.

All photometric calibrators are run in duplicate. If both the % error limit and the absorbance error limit are out of range, a *Dup.E* alarm is issued indicating a failed calibration.

Sensitivity Limit Use these 2 text boxes to define the lower and upper sensitivity limits during the calibration of the selected test.

Type the lower sensitivity limit (-99999 to 999999) in the first text box and press <Enter>. Type the upper sensitivity limit (-99999 to 999999) in the second text box and press <Enter>.

These values specify that a minimum absorbance change must be detected between the blank and span calibrator during calibration of endpoint assays. If the absorbance unit calculated using the blank and span calibrators is not within the sensitivity limits, a *Sens.E* alarm is issued indicating a failed calibration.

S1 Abs. Limit Use these 2 text boxes to define the lower and upper absorbance limit for the calibrator 1, Std (1).

Type the lower absorbance limit (-32000 to 32000) in the first text box and press <Enter>. Type the upper absorbance limit (-32000 to 32000) in the second text box and press <Enter>.

If the absorbance for calibrator 1 falls outside the limits defined in these fields, an *S1A.E* alarm is issued indicating an erroneous calibration.

For those tests that use a Std (1) with a value other than zero, the instrument calculates the expected absorbance at a zero concentration. This value is used to determine *S1A.E* alarms.

Auto Masking Use this check box to activate or deactivate the auto masking function for the application currently selected. If this check box is checked, the application can be automatically masked when a calibration has failed or no valid calibration is available.

See:
Calibration masking (auto masking) on page B-239
Calibration Mask Setting window on page E-392

The **auto masking** function must be activated on the **Utility** > **System** (**Page 2/4**) > **Calib Mask Setting**. This is the main switch to turn on the **Calib Mask** function for the system.

Auto Calibration area

This area contains 3 subareas: **Timeout**, **Changeover** and **QC Violation**. **Timeout** and **QC Violation** are two mutually exclusive options:

Timeout (default setting): Choose this option to activate automatic calibration recommendations at regular intervals. All settings are made in the **Timeout** subarea.

QC Violation: Choose this option to activate QC-triggered calibration recommendations. All settings are made in the **QC Violation** subarea.

Timeout

This option is the default setting. Choose this option to configure and use automatic calibration recommendations at regular intervals (Timeout calibrations). Use the list boxes and corresponding text boxes in this area to define the time intervals between Timeout calibrations.

Lot Use this list box to select the method of lot-to-lot calibration. Selections available are **Blank**, **Span**, **2 Point**, **Full** and **Cancel**.

If **Cancel** is selected, an automatic lot calibration at regular intervals does not take place.

Use the text box to define the regular time intervals for automatic calibration recommendations.

Use the list box to define the unit of the time intervals (**Day** or **Hour**).

Cassette Use this list box to select the method of cassette-to-cassette calibration. Selections available are **Blank**, **Span**, **2 Point**, **Full** and **Cancel**.

If **Cancel** is selected, an automatic cassette calibration at regular intervals does not take place.

Use the text box to define the regular time intervals for automatic calibration recommendations.

Use the list box to define the unit of the time intervals (**Day** or **Hour**).

For more information, see:
Calibration concept on page B-155
Causes for automatic calibration recommendations on page B-156

Changeover

Lot Use this list box to select the method of lot-to-lot calibration. Selections available are **Blank**, **Span**, **2 Point**, **Full** and **Cancel**.

If **Cancel** is selected, an automatic calibration recommendation does not take place when a new lot of reagent is used for the test.

Cassette Use this list box to select the method of cassette-to-cassette calibration. Selections available are **Blank**, **Span**, **2 Point**, **Full** and **Cancel**.

If **Cancel** is selected, an automatic calibration recommendation does not take place when a new bottle of reagent is used for the test.

QC Violation

Choose this option to configure and use QC-triggered calibration recommendations.

Use the boxes in this area to set a confidence range and to preselect the calibration method to be recommended in case of a QC violation through the specified controls.

Method Use this box to select a calibration method (**Blank**, **Span**, **2 Point**, or **Full**).

When the system recommends a calibration due to QC violation, it recommends the calibration method which is preselected here.

Rule Use this box to set the confidence range.

- **1s** denotes a range for acceptable QC results of QC target value ±1 SD, where SD is the application's standard deviation.
- **2s** denotes a range of QC target value ±2 SD.
- **3s** denotes a range of QC target value ±3 SD.

The actual values for the QC target value, SD, and the confidence limits are displayed on the **QC** > **Install** screen.

For more details on editing confidence limits, see *Editing control values* on page B-224.

Control Up to 3 different controls can be selected for each application. At least 1 control must be selected to get a valid configuration.

Choose the arrow in the control box(es) to open a list of available controls. This list shows all controls that supply target and SD values for the currently selected test. Select a control from the list.

Calib. (e 601 tests)

➔ **Utility** > **Application** > **e** 601 test (141-200 on **Test** list) > **Calib.**

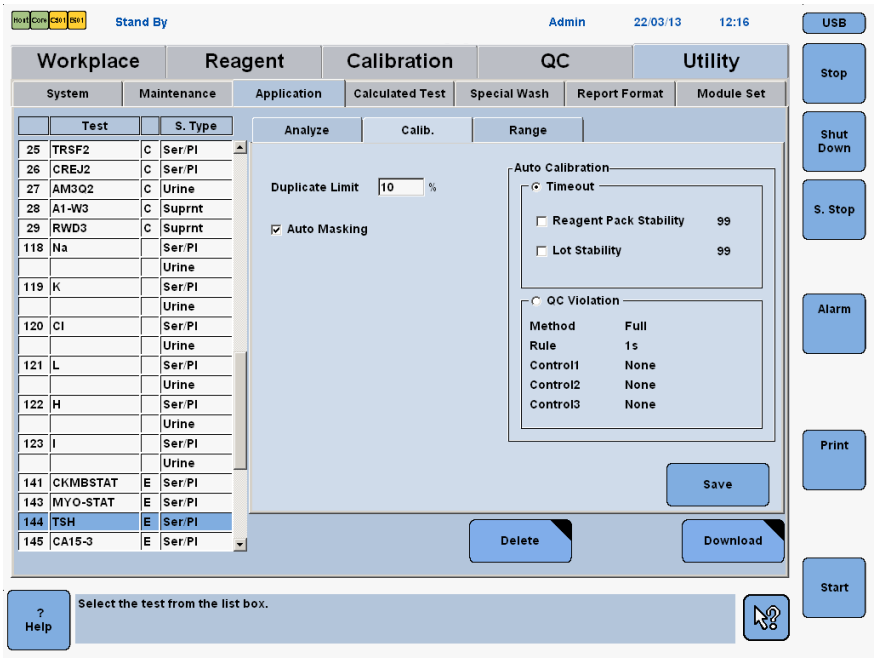


Figure E-312 Calib. tab (**e** 601)

Use this screen to display calibration parameters for a selected test on an **e** 601.

For information on the **Test** list and **Delete** and **Download** buttons, see *Test list* on page E-484.

Duplicate Limit

Use this text box to define the maximum acceptable difference of the duplicated calibrator measurements of level one and level two for the selected application.

If duplicated calibrator measurements are outside of this limit, the calibration is failed.

Do not change the default values. Contact the Roche service representative if you want to change this value.

Auto Masking

Use this check box to activate or deactivate the auto masking function for the selected application.

If this check box is checked, the application can be automatically masked when a calibration has failed or no valid calibration is available.

See:
Calibration masking (auto masking) on page B-239
Calibration Mask Setting window on page E-392

The **auto masking** function must be activated on the **Utility** > **System** (**Page 2/4**) > **Calib Mask Setting**. This is the main switch to turn on the **Calib Mask** function for the system.

Auto Calibration area

This area contains two subareas: **Timeout** and **QC Violation**. **Timeout** and **QC Violation** are two mutually exclusive options:

Timeout (default setting): Choose this option if you want to work with a time interval to perform a calibration to be updated. The system recommends calibrations at regular intervals. For the immune applications this information comes from the 2 dimensional barcode on the **cobas e** packs (for details please refer to the package insert of the test). To change the default time intervals for lot and reagent pack calibrations use this area.

QC Violation: Choose this option to activate QC-triggered calibration recommendation by the system. All settings are made in the **QC Violation** subarea.

Timeout

Choose this option (default setting) to configure and use automatic calibration recommendations at regular intervals (timeout calibrations). Use the 2 check boxes and corresponding text boxes in this area to change the default values for timeout calibrations for the selected application. Before you change any values ensure you have read and understood the package insert of the test/application.

Reagent Pack Stability Select this check box to change the default reagent pack calibration stability and enter a user specific time interval. After this time interval the system automatically recommends to perform a new reagent pack calibration. If the check box is not selected, the encoded stability in the reagent barcode (7 days in most cases) is used.

Enter the period of time, in days, in the text box for which the reagent pack calibration is valid.

Lot Stability Select this check box to change the lot calibration stability and enter a user specific time interval. After this time interval the system automatically recommends to perform a new lot calibration. If the check box is not selected, the encoded stability in the reagent barcode (28 days in most cases) is used.

Enter the time period, in days, in the text box for which the lot calibration is valid.

QC Violation

Choose this option to activate QC-triggered calibration recommendation.

Use the boxes in this area to set a confidence range and to define the calibration method to be recommended by the system in case the specified controls are out of the confidence limit.

Method Use this box to select a calibration method. When the system recommends a calibration due to QC violation, it recommends the calibration method which is preselected here. For the **e** 601 applications only the method **Full** is available.

Cancel means no calibration is recommended by the system if the control result is out of the confidence limit.

Rule Use this box to set the confidence range.

- **1s** denotes a range for acceptable QC results of QC target value ±1 SD, where SD is the application's standard deviation.
- **2s** denotes a range of QC target value ±2 SD.
- **3s** denotes a range of QC target value ±3 SD.

The actual values for the QC target value, SD, and the confidence limits are displayed on the **QC** > **Install** screen. Verify that the defined range of 1 SD, 2 SD or 3 SD is used there for the confidence range. If necessary press the **Calculate** button in the **QC** > **Install** > **Edit** screen to update the confidence limit.

For more details on editing confidence limits, see *Editing control values* on page B-224.

Control Up to 3 different controls can be selected for each application. At least 1 control must be selected to have a valid configuration.

Choose the drop down list in the **Control** box(es) to open a list of available controls. This list shows all controls that are linked and supply target and SD values for the selected test. Select a control from the list.

Range (c 501 ISE and photometric tests)

➔ **Utility** > **Application** > photometric test (1-117 on **Test** list) > **Range**

If the field is grayed out, the field is read only for the password level logged onto the system. At an administrator level, if the field is not grayed out, it can be edited.

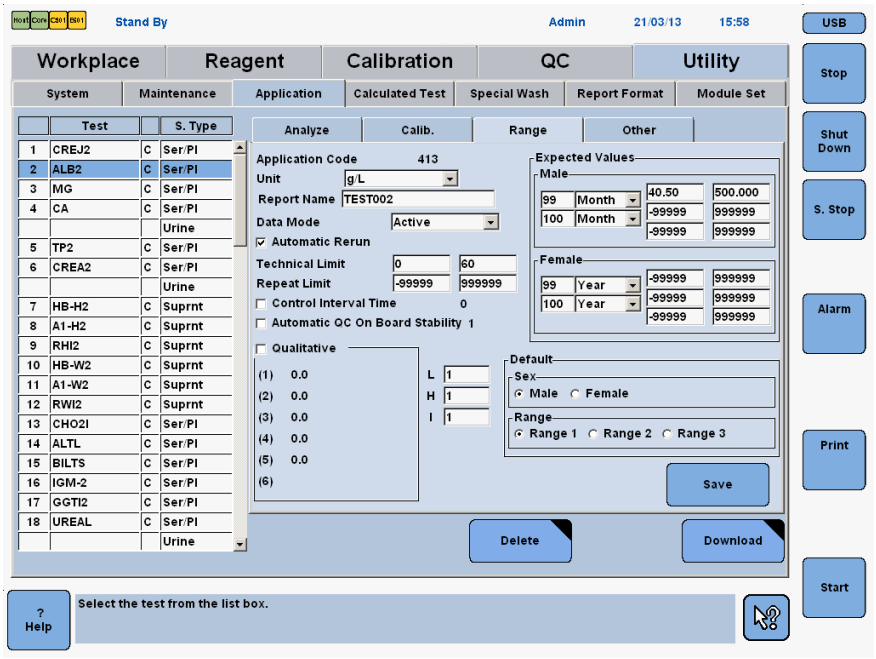


Figure E-313 Range tab (photometric application)

Use this screen to display the application code, report name, data mode, control intervals, technical limit, repeat limit and expected values for each test.

For information on the **Test** list and **Delete** and **Download** buttons, see *Test list* on page E-484.

Application Code This field displays the application code number for the selected test.

Unit This box displays the used unit of measure for the selected test. Use this box to change the unit.

This unit can be changed only once by using the drop down list and select a different unit. After the unit is changed the field is not a drop down list any more.

For more information on changing the unit of measure, see *To change the unit of measure for a previously calibrated c 501 application* on page B-270.

Report Name Use this text box to define the test name that will appear on the patient reports. Type the report name (up to 22 characters) and press <Enter>.

*Data Mode (**c** 501 (P) only)* Use this list box to specify whether a test is performed on board the module or performed manually with the results entered into the patient report later. In the case of **c** 501 (ISE), on board status is the only status, so this field does not appear.

- Select the **Active** option for tests performed on the module.
- Select the **Inactive** option for tests performed manually.

Automatic Rerun

Use this check box to select or deselect automatic reruns for this application.

If automatic rerun is selected, the sample will be rerun by the system if the result for this test have a data flag according to the rerun list or the **Repeat Limit** conditions are fulfilled.

The main switch for **Automatic Rerun** needs to be activated on the **Start Conditions** screen. The test will be automatically repeated if both switches are activated.

For more information, see:
Processing reruns on page B-67
Rerun list on page D-63

Technical Limit

Use these 2 text boxes to define the lower and upper technical limits for the selected test. Type the lower limit (-99999 to 999999) in the first text box and press <Enter>. Type the upper limit (-99999 to 999999) in the second text box and press <Enter>.

Any result outside the limits specified here is flagged with a >*Test* or <*Test* data alarm.

If the automatic rerun function is selected on the **Start Conditions** screen, results exceeding the defined upper limit are automatically rerun with the reduced sample concentration or as a diluted sample as specified in the **Dec.** fields in **Utility** > **Application** > **Analyze**. Results below the defined lower limit are rerun with the increased sample concentration as specified in the **Inc.** fields in **Utility** > **Application** > **Analyze**.

The technical limit downloaded from the application's e-barcode reflects the linearity of the test. Technical limits are based on the normal sample volume.

Repeat Limit

Use these 2 text boxes to define the lower and upper repeat limits for the selected test. Type the lower limit (-99999 to 999999) in the first text box and press <Enter>. Type the upper limit (-99999 to 999999) in the second text box and press <Enter>.

Any result outside the specified limits is flagged with a >*Rept* or <*Rept* data alarm.

Any result outside this limit is repeated if the automatic rerun is activated (using the normal sample volume). In **Utility** > **System** > **Alarm** (**Page 1/4**) you can enable the main switch for the repeat limit check. The test will be automatically repeated if the settings for the automatic rerun are activated.

See *Alarm Setting window* on page E-374.

Control Interval Time

Use this check box and the corresponding text box to define the time period to repeatedly run controls for the selected test.

Select the check box to enable the timeout control function. If the check box is blank, the function is disabled.

Specify the time period in hours when the test should be controlled. At the end of the time period (1 to 1000 hours) a QC measurement is automatically requested (Cause: Timeout) by the system or an auto QC measurement is triggered.

See *Automatic QC measurement* on page B-228.

Automatic QC On Board Stability

Use this check box and corresponding text box to define the on board stability for the control material on the rack rotor for the selected test.

If AutoQC racks are used and a control material stability expires (On Board stability exceeded), the system displays the yellow alarm. Please refer to the instructions for use of the application and the control to find out the stability of the parameter in the control material.

See *Automatic QC measurement* on page B-228.

L, H, I (serum index)

The serum index function can be defined individually for each photometric and ISE test. In the serum index fields **L** (lipemic), **H** (hemolytic), **I** (icteric) the limits that are loaded with the application are displayed. For the ISE applications the limits have to be entered manually.

See *To define serum indices* on page B-273.

Limits for **H**, **I** and **L** index are implemented in conventional units in all application settings. When using international units for **H**, **I** and **L** index the respective serum index limits have to be changed in all applications.

If at least one serum index field has a value other than **0**, serum indices are calculated. If **0** is entered, the corresponding serum index is not calculated.

- To use the serum index function, the serum index application must be installed and the serum index requested on the **Workplace** > **Test Selection** screen.
- If one of the measured serum indices exceeds the limit entered on the **Range** tab, a data alarm *>I.xxx* (for example I.LH) is attached to the result of the test.
- The serum index test and the ISE tests could be performed on different **c** 501 modules, if you use a **cobas** 6000 analyzer with two **c** 501 modules.

Qualitative area

Select the check box to enable the qualitative evaluation function.

If the check box is blank, the qualitative evaluation is disabled. If enabled, text boxes (1) through (6) are active.

(1) through (5)

Use the first text box to define the upper limit for range 1. This range does not appear on the patient report. Type the upper limit (-99999 to 999999) and press <Enter>. Any result less than or equal to the value defined here prints the text defined in the second text box.

Use the second text box to define the characters that print on the patient report. Up to 6 characters (such as --, ++, +-, or +++) can be entered.

Type the desired characters and press <Enter>.

(6)

Use this text box to define the characters that print on the patient report for results above the upper limit of range 5. Up to 6 characters (such as --, ++, +-, or +++) can be entered. Type the desired characters and press <Enter>.

Application screen

Expected Values area

Use the **Expected Values** area to define the reference ranges for women and men in 3 different age groups. If a result for this test is outside of the defined ranges, the result receives a data alarm.

Male In the first two text boxes enter an age range in **Day**, **Month**, or **Year**. To the right of the age range there are three lines for expected values.

- In the first line you define the expected values below the age range.
- In the second line you define the expected values for the specified age range.
- In the last line you define the expected values above the age range.

If you don't want to have the data alarm for any of these ranges enter -99999 to 999999.

Female In the first two text boxes enter an age range in **Day**, **Month**, or **Year**. To the right of the age range there are three lines for expected values.

- In the first line you define the expected values below the age range.
- In the second line you define the expected values for the specified age range.
- In the last line you define the expected values above the age range.

If you don't want to have the data alarm for any of these ranges enter -99999 to 999999.

Default area

Sex Use these 2 options to select either **Male** or **Female** values to be used as the default expected values if sex is not defined for a sample. Select the **Male** option or **Female** option.

Range Use these 3 options to select which range of values to use as the default expected values if age is not defined for a sample. Select the range (**Range 1**, **Range 2**, or **Range 3**) and press <Enter>.

Range (e 601 tests)

➔ **Utility** > **Application** > **e** 601 test (141-200 on **Test** list) > **Range**

If the field is grayed out, the field is read only for the password level logged onto the system. At an administrator level, if the field is not grayed out, it can be edited.

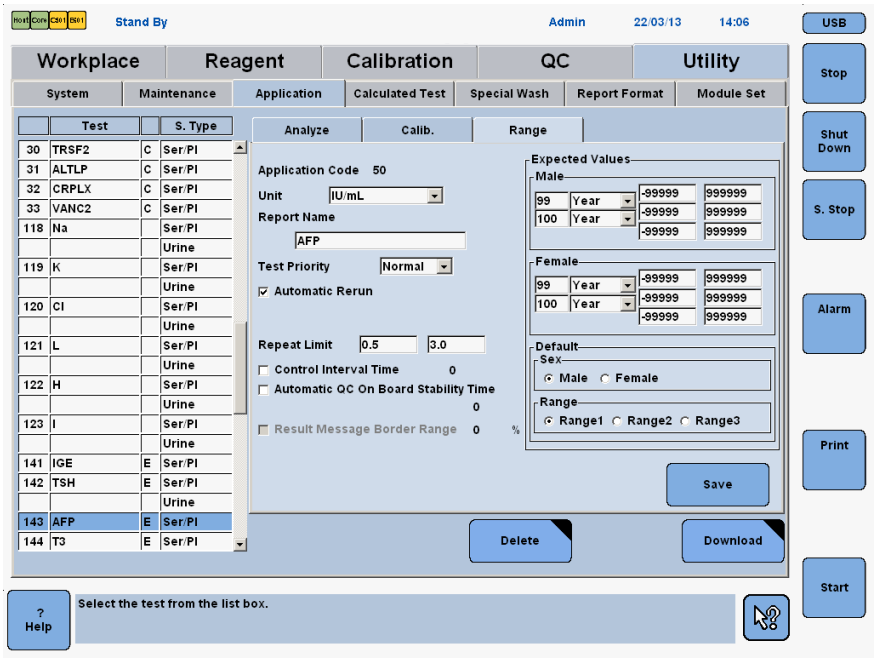


Figure E-314 Range tab (**e** 601 application)

Use this screen to display the application code, report name, test priority, control intervals, repeat limit and expected values for each test.

For information on the **Test** list and **Delete** and **Download** buttons, see *Test list* on page E-484.

Application Code This field displays the application code number for the selected test.

Unit This box displays the used unit for the selected test. Use this box to change the unit.

This unit can be changed only once by using the drop down list and select a different unit. After the unit is changed the box is not a drop down list any more.

For more information on changing the unit of measure, see *To change the unit of measure for a previously calibrated c 501 application* on page B-270.

Report Name Use this text box to define the test name that will appear on the patient reports. Type the report name (up to 22 characters) and press <Enter>.

Test Priority Use this list box to select the priority level for the selected test. Available levels are **High** (this test will be processed first on **e** 601) and **Normal**.

The default settings come from **cobas** link. If these settings are changed the rack flow of the system is influenced. If you change a high priority test to a normal priority results might be influenced (please refer to the instructions for use).

Automatic Rerun

Use this check box to select or deselect automatic reruns for this application.

If automatic rerun is selected, the sample will be rerun by the system if the result for this test have a data flag according to the rerun list or the **Repeat Limit** conditions are fulfilled.

The main switch for **Automatic Rerun** needs to be activated on the **Start Conditions** screen. The test will be automatically repeated if both switches are activated.

For more information, see:
Processing reruns on page B-67
Rerun list on page D-63

Repeat Limit

Use these 2 text boxes to define the lower and upper repeat limits for the selected test. Type the lower limit (-99999 to 999999) in the first text box and press <Enter>. Type the upper limit (-99999 to 999999) in the second text box and press <Enter>.

Any result outside the specified limits is flagged with a >*Rept* or <*Rept* data alarm.

Any result outside this limit is repeated if the automatic rerun is activated (using the normal sample volume). In **Utility** > **System** > **Alarm** (**Page 1/4**) you can enable the main switch for the repeat limit check. The test will be automatically repeated if the settings for the automatic rerun are activated.

See *Alarm Setting window* on page E-374.

Control Interval Time

Use this check box and the corresponding text box to define the time period to repeatedly run controls for the selected test.

Select the check box to enable the timeout control function. If the check box is blank, the function is disabled.

Then specify the time period in hours when the test should be controlled. At the end of the time period a QC measurement is automatically requested (Cause: Timeout) by the system or an auto QC measurement is triggered.

See *Automatic QC measurement* on page B-228.

Automatic QC On Board Stability

Use this check box and corresponding text box to define the on board stability for the control material on the rack rotor for the selected test.

If AutoQC racks are used and a control material stability expires (On Board stability exceeded), the system displays the yellow alarm. Please refer to the instructions for use of the application and the control to find out the stability of the parameter in the control material.

See *Automatic QC measurement* on page B-228.

Expected Values area

Use the **Expected Values** area to define the reference ranges for women and men in 3 different age groups. If a result for this test is outside of the defined ranges, the result receives a data alarm.

Male In the first two text boxes enter an age range in **Day**, **Month**, or **Year**. To the right of the age range there are three lines for expected values.

- In the first line you define the expected values below the age range.
- In the second line you define the expected values for the specified age range.
- In the last line you define the expected values above the age range.

If you don't want to have the data alarm for any of these ranges enter -99999 to 999999.

Female In the first two text boxes enter an age range in **Day**, **Month**, or **Year**. To the right of the age range there are three lines for expected values.

- In the first line you define the expected values below the age range.
- In the second line you define the expected values for the specified age range.
- In the last line you define the expected values above the age range.

If you don't want to have the data alarm for any of these ranges enter -99999 to 999999.

Default area

Sex Use these 2 options to select either **Male** or **Female** values to be used as the default expected values if sex is not defined for a sample. Select the **Male** option or **Female** option.

Range Use these 3 options to select which range of values to use as the default expected values if age is not defined for a sample. Select the range (**Range 1**, **Range 2**, or **Range 3**) and press <Enter>.

Other (c 501 ISE tests)

➔ **Utility** > **Application** > ISE test (118-120 on **Test** list) > **Other**

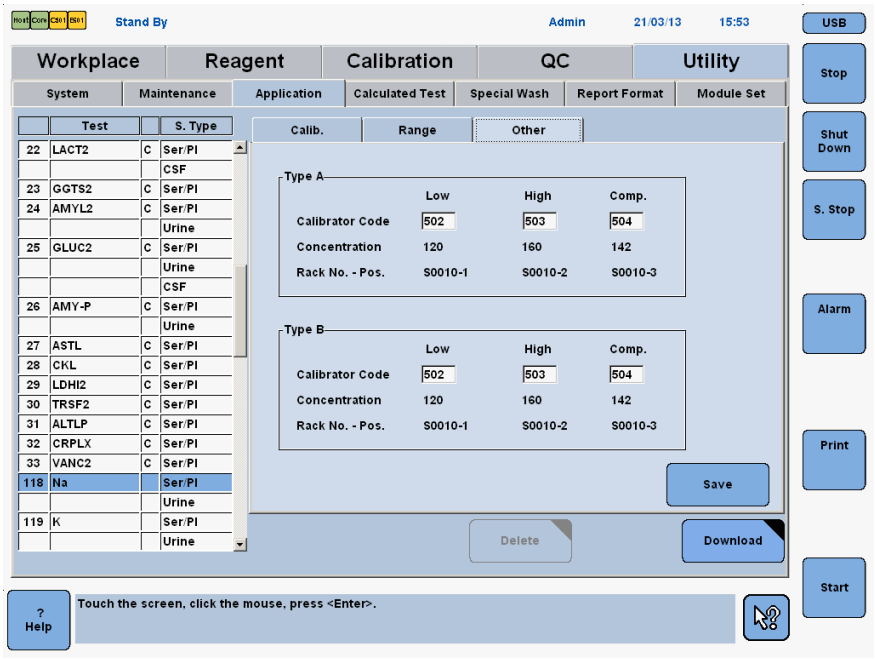


Figure E-315 Other tab (ISE test)

Use this tab to set up two independent sets of calibration curves for different sample types for each ISE test Na^+, K^+, and Cl^-. Choose an ISE test from the test list to display calibrator codes, concentration values, and rack position numbers.

For information on the **Test** list and **Delete** and **Download** buttons, see *Test list* on page E-484.

The **Other** tab contains two areas, **Type A** and **Type B**, where each area relates to one of the two independent calibration curves in **Utility** > **System** (**Page 3/4**) > **ISE Calib Setting**. In case two different calibration curves are used, different calibrator codes are entered for **Type A** and **Type B**.

To use these calibration curves for a specific sample type, you must assign an ISE calibration curve for each sample type.

For more information, see:
ISE Calibration Setting window on page E-411
Calibration concept - ISE applications on page B-159
ISE calibration on page B-193
Setting up individual calibration curves for each ISE sample type on page B-276

If the field is grayed out, the field is read only for the password level logged onto the system. At an administrator level it can be edited.

Type A/ Type B This area displays the two different calibration curve types for ISE.

Calibrator Code Use these text boxes to define the calibrator codes (1 to 998) for each calibrator, **Low**, **High** and **Comp**.

If only one calibration curve type is used—if you use the same calibration curve for all sample types— then you must enter the same calibrator codes for **Type A** and **Type B**. It is not possible to inactivate one of the calibrator curves.

Concentration These fields display the concentrations of each individual calibrator as defined on the **Calibration** > **Install** screen.

Rack No.-Pos. These fields display the rack number and sample position of each calibrator.

Other (c 501 photometric tests)

➔ **Utility** > **Application** > photometric test (1-117 on **Test** list) > **Other**

If the field is grayed out, the field is read only for the password level logged onto the system. At an administrator level, if the field is not grayed out, it can be edited.

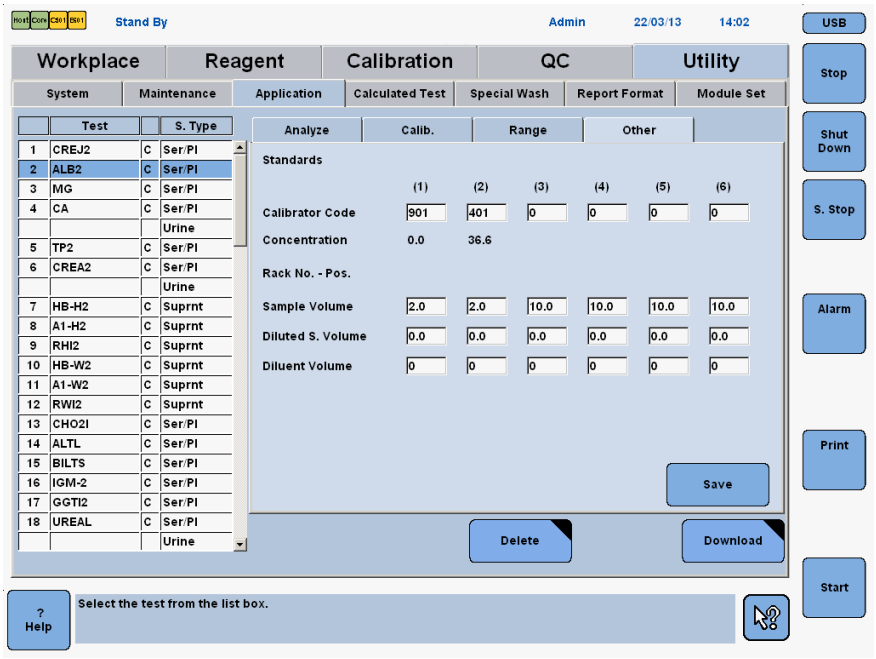


Figure E-316 Other tab (photometric test)

Use this screen to display or define additional test parameters such as calibrator code, calibrator target values, calibrator position, sample volumes, diluent volumes and diluted sample volumes.

For information on the **Test** list and **Delete** and **Download** buttons, see *Test list* on page E-484.

(1) through (6) These columns display the 6 possible calibrator standards.

Calibrator Code Use these text boxes to define the calibrator codes for each standard (1 to 6). Type the calibrator code (1 to 998) and press <Enter>.

Type 0 to indicate no calibrator.

Concentration These fields display the concentrations of each individual calibrator as defined on the **Calibration** > **Install** screen.

Rack No.-Pos. These fields display the rack number and sample positions of each calibrator.

Sample Volume Use these text boxes to define the normal sample volumes of each calibrator as it is transferred from the vessel to the reaction cell.

Type the sample volume in microliters and press <Enter>.

*Diluted S. Volume (**c** 501* (P) *only)* Use these text boxes to define the volume of diluted standard dispensed for calibration. Type the diluted volume and press <Enter>.

Type **0** to indicate no diluted sample volume is used.

*Diluent Volume (**c** 501* (P) *only)* Use these text boxes to define the volume of diluent dispensed for dilution. Type the volume and press <Enter>.

Type "**0**" to indicate no diluent is used.

Application Parameter Delete window

➔ **Utility** > **Application** > **Delete**

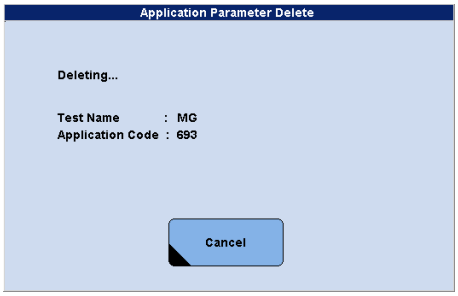


Figure E-317 Application Parameter Delete window

This window is displayed while application parameters are being deleted.

Test Name This field displays the test name of the application.

Application Code This field displays the ACN of the application.

Download window

➔ **Utility** > **Application** > **Download**

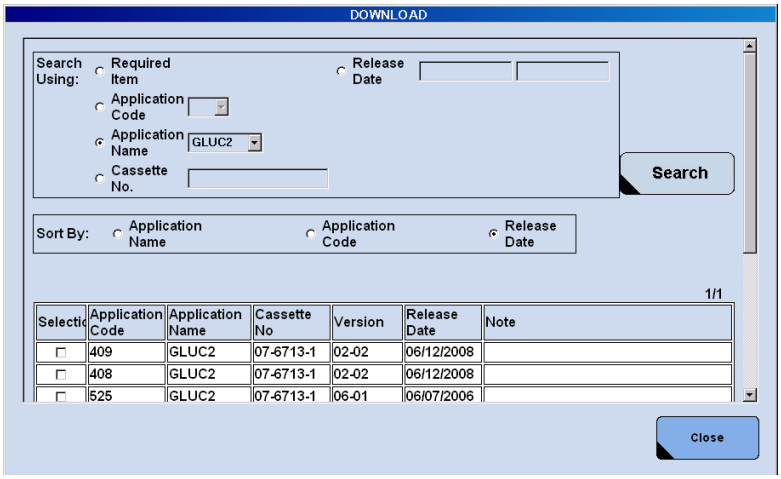


Figure E-318 Download window

This window is displayed when the system is ready to download additional application parameters via **cobas** link. Use this window to download additional application parameters.

For more information, see:
Installing an application on page B-252
Downloading new application parameters on page B-255
Updating an application on page B-258

Update of editable application parameters

If an application's e-barcode is downloaded from **cobas** link while another e-barcode (same or other version) for the same ACN is already present on the system, most of the editable application parameters, including text fields, check boxes, drop down menus and option buttons are not overwritten.

Exceptions:

- For **c** 501 editable parameters in the **Other** tab (**Calibrator Code** and pipetting volumes) and serum index values (**Range** tab) are overwritten.
- For **e** 601 the settings in the **QC Violation** area as well as the values for **Repeat Limit** and **Expected Values** always jump back to default.

There is no indication in the software if the editable parameter originates from the old or new e-barcode or has been manually entered. Therefore check the application parameters after overwriting.

In order to make sure that all application parameters are according to the new application's e-barcode, Roche Diagnostics recommends to delete the current application before downloading the new one. Perform calibration and control before you resume routine operation.

Search Using area

Required Item An item has not been found in the instrument at the time of reagent barcode reading. For measurements necessary parameters must be downloaded (no function for **e** 601).

Release Date Use this option to download the newest test parameters.

Application Code Use this option to select the application code from the list box.

Application Name Use this option to select the application name from the list box.

Cassette No. Use this option to select the **Cassette No.** of the application parameters. (**c** 501 only)



Cassette No., Code, system-ID

Various terms for **Cassette No.** are used:

- **Cassette No.** on the **Download** window
- **Code** in the **Cassette Configuration** area on the **Utility** > **Application** > **Analyze** screen.
- System-ID on **cobas c** packs

Search button Use this button to search the application test parameters.

After a successful search a selection table appears in the lower half of the window. This table displays all application test parameters that match the search criteria.

Sort By area

Use this function for changing the display order in the list, select either **Application Name** or **Application Code** or **Release Date**.

Application Name Use this function to sort the application list by application name.

Application Code Use this function to sort the application list by application code.

Release Date Use this function to sort the application list by release date.

Download area

Use this area to select the desired item for download.

[Next>] Choose **[Next >]** to display more search results.

Page/pages Depending on the number of items in the table there can be more than one page. For example, the information **2/3** means that page 2 of 3 is displayed.

Selection Use this check box to define which of the items in the table is to be downloaded. You can select more than one.

Application Code This column displays the application code.

Application Name This column displays the application name.

Cassette No. This column displays the **Cassette No.** of the application parameters (**c** 501 only). If the test changed, a version number is displayed. It is possible that two versions are available at the same time.

Version This column displays the version number of the downloaded test application.

Release Date This column displays the release date of the application.

Note In the column **Note** you can find additional information about the application test parameters.

Download Use this button to start the download of the selected items.

Depending on the number of items in the list there can be more than one page. For example the information **2/3** means you are on page two of three pages.

Confirmation window

➔ **Utility** > **Application** > **Download** > **Search** > **Download**

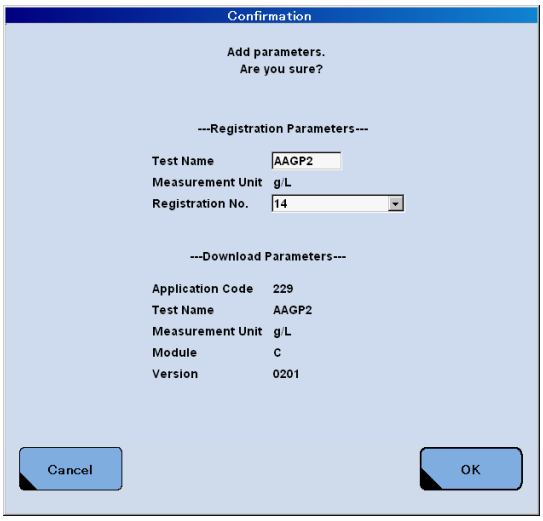


Figure E-319 Confirmation window (new photometric application)

This window is used to confirm the message on the confirmation window to start the download.

Test Name This field displays the short test name assigned to the application code downloaded from **cobas** link. To edit this test name (not for **e** 601), type a test name with up to 5 characters.

Changing of the Test Name (c 501)

Once the application has been downloaded, the test name cannot be changed. In order to change the test name, the application needs to be deleted and downloaded again.

Measurement Unit This field displays the default unit for this test.

For more information, see:
To change the unit of measure for a previously calibrated c 501 application on page B-270
Unit on page E-503
Unit on page E-507

Registration No. The **Registration No.** list box is the test sequence number of the **Test** list on the **Utility** > **Application** screen. The test sequence number can influence the priority of sampling on the **c** 501 module.

However, it is possible to choose a different number from the **Registration No.** list box to modify the test sequence. To optimize the consumption of wash solution and the throughput of the system it is recommended to order the tests depending on their sensitivity against carryover. Tests with a sensitivity against carryover should not be pipetted immediately one after another.

A current carryover prevention list is available on **cobas** link. Refer to the instructions for use for NaOH-D / SMS / Sample Cleaner 1 or 2 / SCCS.

Application Code This field displays the application code.

Test Name This field displays the default test name.

Module This field displays the information on which module this application is used.

Version This column displays the version number of the downloaded test application.

Calculated Test screen

➔ **Utility** > **Calculated Test**

This screen is only available if a **c** 501 is part of the system. This screen can be viewed by an operator with a supervisor level, but an administrator level is required to edit the data.

This area is not available if you have an E or EE combination. It is not possible to program calculated or compensated formulas for **e** 601 applications.

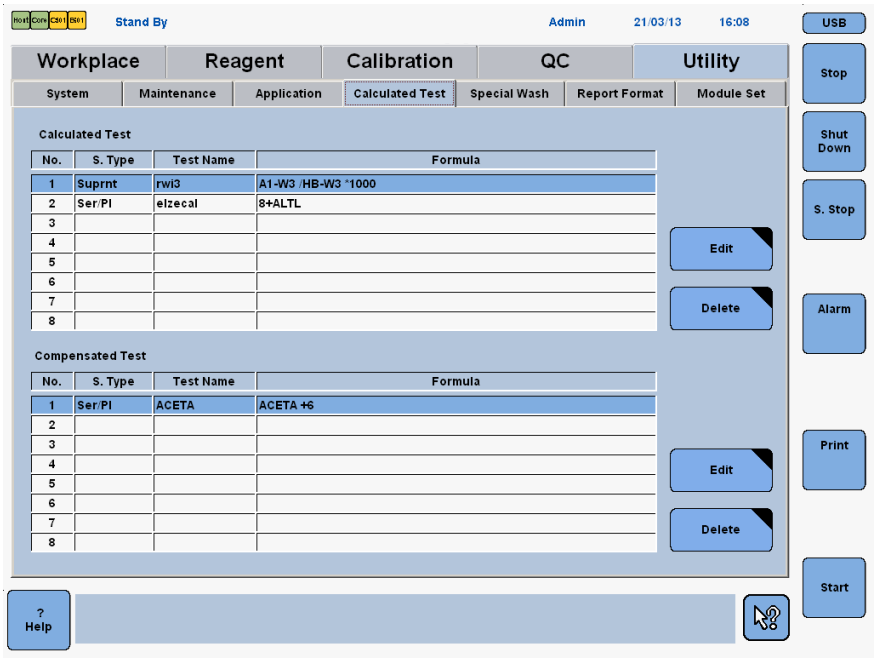


Figure E-320 Calc. Test screen

Use this screen to define calculated or compensated test formulas. A calculated test result is not actually performed on the system, but calculated from other test results that have been run on the system. A compensated test result has been performed on the system and has been modified by the compensated formula.

For more information, see:
Programming calculated tests on page B-292
Programming compensated tests on page B-295
Calculated Test Formula window on page E-523
Compensated Test Formula window on page E-527

Calculated Test area

8 possible positions for the test calculation are available in the **Calculated Test** list at the top of the screen.

If calculated tests have been programmed before, they are displayed in the **Calculated Test** list. This result is displayed in **Workplace** > **Data Review** as soon as all results for the test used in the formula are available.

No. The **No.** column displays the number of the programmed formula.

S. Type The **S. Type** column displays the sample type.

Test Name The **Test Name** column displays the name of the formula as specified by the user.

Formula The **Formular** column displays how the results is calculated.

Buttons

Edit Choose this button, located to the right of the **Calculated Test** list, to display the **Calculated Test Formula** window.

Use this window to add a new test calculation.

See *Calculated Test Formula window* on page E-523.

Delete Choose this button, located to the right of the **Calculated Test** list, to delete the calculated test formula selected in the **Calculated Test** list, after confirmation.

Compensated Test area

An additional 8 positions for the test compensation are available in the **Compensated Test** list at the bottom of the screen.

If compensated tests have been programmed already, they are displayed in the **Compensated Test** list. Select an open space in the **Compensated Test** list to define a new compensated test formula. This substitutes a result in **Workplace** > **Data Review** as soon as all results for the test used in the formula are available.

No. The **No.** column displays the number of the formula specified by the user.

S. Type The **S. Type** column displays the sample type.

Test Name The **Test Name** column displays the test name of which the result is substituted in **Workplace** > **Data Review** as soon as all test results in the formula are available.

Formula The **Formular** column displays how the result is calculated.

Buttons

Edit Choose this button, located to the right of the **Compensated Test** list, to display the **Compensated Test Formula** window.

Use this window to add a new test calculation.

See *Compensated Test Formula window* on page E-527.

Delete Choose this button, located to the right of the **Compensated Test** list, to delete the compensated test formula selected in the **Compensated Test** list, after confirmation.

Calculated Test Formula window

➔ **Utility** > **Calculated Test** > line (in **Calculated Test** list) > **Edit** (top right)

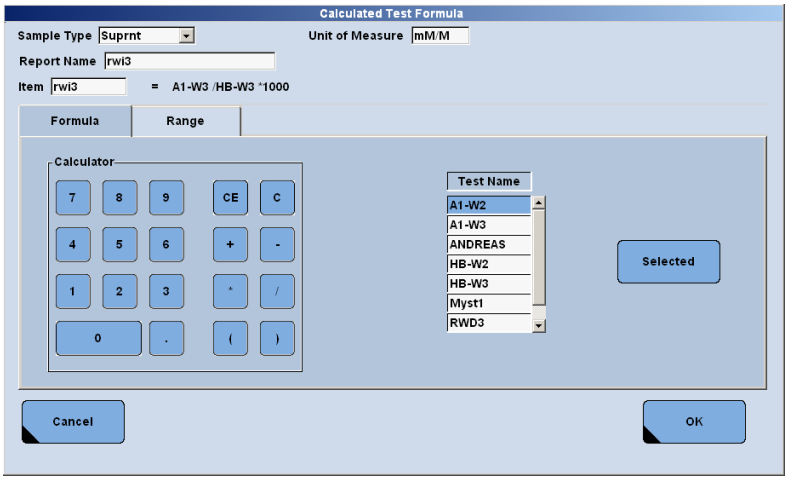


Figure E-321 Calculated Test Formula window

Use this window to edit or define formulas and parameters for calculated tests.

Calculated tests are only valid for **c** 501 assays.

Sample Type Use this list box to select the sample type (**Ser/Pl**, **Urine**, **CSF**, **Suprnt** or **Other**).

Unit of Measure Use this text box to specify the unit used for the calculated test result.

Report Name Use this text box to define the report name for the calculated test that is printed on the patient report.

Item Use this text box to define the name of the calculated test. Only alphabetic and numerical characters can be used.

Selected By pressing this button you transfer the selected test name in the list to the formula.

Formula tab

➔ **Utility** > **Calculated Test** > **Edit** (top right) > **Formula**

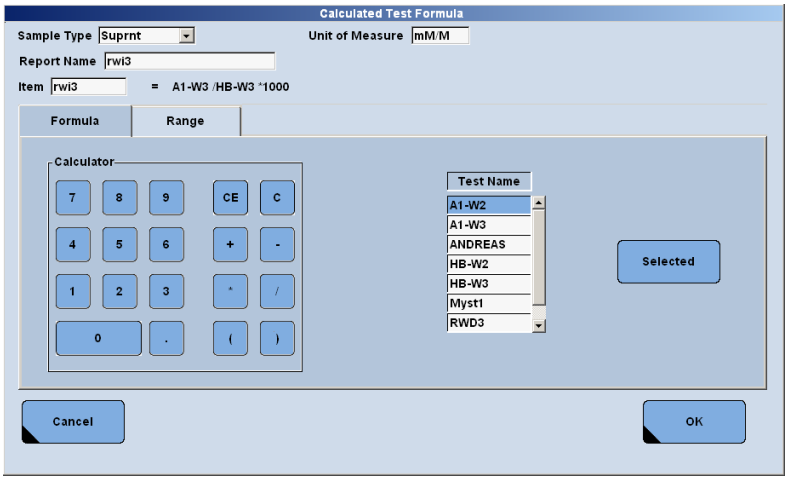


Figure E-322 Calculated Test Formula window

All tests that are available to be used in a calculation are displayed in the **Test Name** list. Choose the number keys and the operator keys in the **Calculator** area to define the formula.

Calculator and Test areas

The formula must be entered according to the following instructions:

- To add a test to the formula, select a test that is part of the formula from the **Test Name** list and choose **Selected** to add the test to the formula.
- To add mathematical operators and numerals, use the **Calculator** area in the window to enter the required operators and numerals in the correct sequence along with test names until the formula is complete.
- Choose **OK** to confirm the defined formula.

 The formula defined is displayed in the area to the right of the **Item** text box on the **Calculated Test Formula** window.

For detailed instructions, see *Programming calculated tests* on page B-292.

Range tab

➔ **Utility** > **Calculated Test** > **Edit** (top right) > **Range**

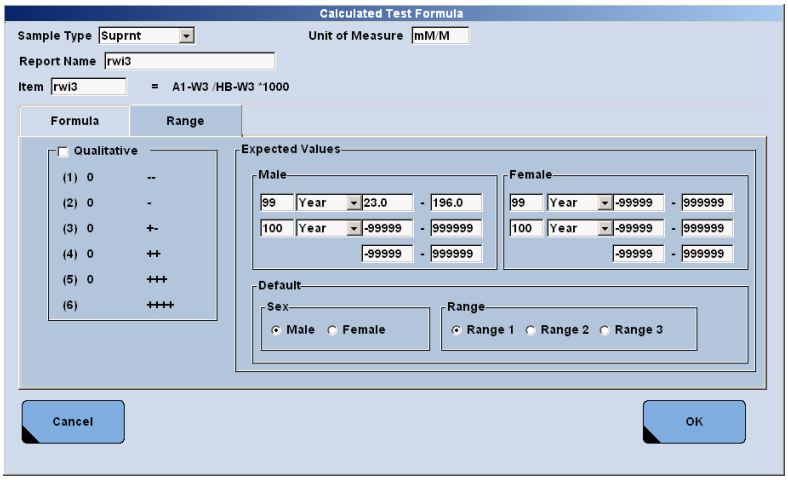


Figure E-323 Range tab of Calculated Test Formula window

Qualitative Select this check box to specify a qualitative evaluation is displayed on the patient report instead of a numerical result.

If enabled, text boxes (1) through (6) are active.

(1) through (5) Use the first text box to define the upper qualitative limit for range 1 (-99999 to 999999). This range does not appear on the patient report. Any result less than or equal to the value defined here will print the text defined in the second text box.

Use the second text box to define the characters that will print on the patient report. Up to 6 characters (such as -, ++, +--, ++++) can be entered. If a blank space is entered, the quantitative numerical value is printed on the report.

(6) Use this text box to define the qualitative characters that will print on the patient report for results above the upper qualitative limit of range 5. Up to 6 characters (such as -, ++, +-, ++++) can be entered. If a blank space is entered, the quantitative value is printed on the report.

Expected Values area

Use the **Expected Values** area to define the reference ranges for women and men in 3 different age groups. If the results for this test fall outside the ranges entered here, the system issues an alarm.

Male Enter in the first two text boxes an age range in **Day**, **Month**, or **Year**. In the following there are three lines for expected values.

- In the first line you define the expected values below the age range.
- In the second line you define the expected values for the specified age range.
- In the last line you define the expected values above the age range.

If you don't want to have the data alarm for any of these ranges enter -99999 to 999999.

Female Enter in the first two text boxes an age range in **Day**, **Month**, or **Year**. In the following there are three lines for expected values.

- In the first line you define the expected values below the age range.
- In the second line you define the expected values for the specified age range.
- In the last line you define the expected values above the age range.

If you don't want to have the data alarm for any of these ranges enter -99999 to 999999.

Default area

Sex area Select an option (**Male** or **Female**) to be used as the default expected values if sex is not defined for a sample.

Range area Select the range of values (**Range 1**, **Range 2**, or **Range 3**) to be used as the default expected values if age is not defined for a sample.

Compensated Test Formula window

➔ **Utility** > **Calculated Test** > line (in **Compensated Test** list) > **Edit** (lower part of the screen)

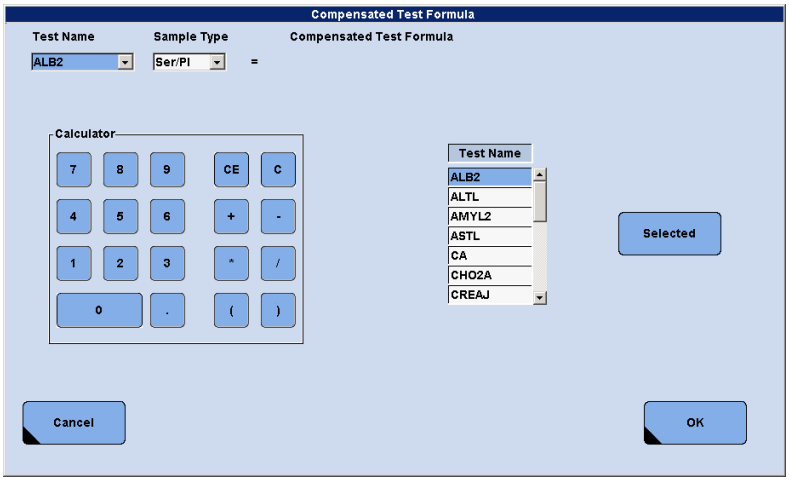


Figure E-324 Compensated Test Formula window

Use this window to edit or define formulas and parameters for compensated tests.

Test Name Use this list box to select the test for which the test compensation is to be performed.

Sample Type Use this list box to select the corresponding sample type for which the test compensation is to be performed.

Compensated Test Formula This field displays the formula you are defining for the compensated test.

Selected By pressing this button you transfer the selected test name in the list to the formula.

Calculator and Test areas

All tests that are available to be used in a calculation are displayed in the **Test Name** list. Choose the number keys and the operator keys in the **Calculator** area to define the formula. The formula must be entered according to the following instructions:

- Select the first test from the **Test Name** list, then choose the **Selected** button or choose the desired numerical value.
- Choose the desired operator key(s) in the **Calculator** area.
- Select the second test from the **Test** list, then choose the **Selected** button or choose the desired numerical value.
- Choose the **OK** button to confirm the defined formula. The formula defined is displayed in the **Compensated Test Formula** field.

👁 For detailed instructions, see *Programming compensated tests* on page B-295.

Special Wash screen

➔ **Utility** > **Special Wash**

The **Utility** > **Special Wash** > **Chemistry** screen is not available on systems without a **c** 501. This screen can be viewed by an operator with a supervisor level, but an administrator level is required to edit the data.

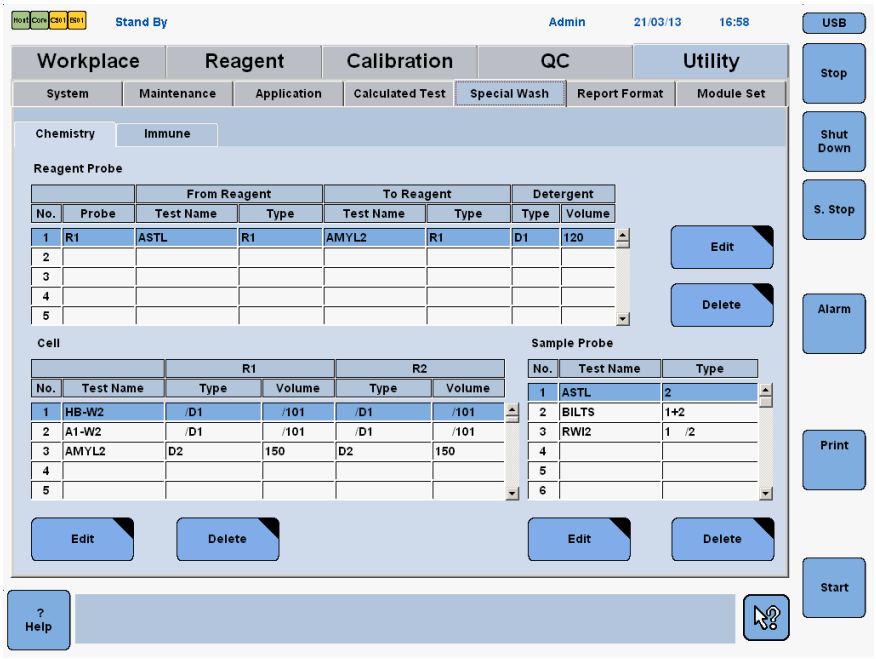


Figure E-325 Special Wash screen

This screen is used to program special wash instructions for the reagent probes, reaction cells and the sample probe on a **c** 501 (P) as well as the reagent probe on an **e** 601. It comprises two tabs:

- Chemistry tab for special wash instructions performed on a **c** 501 (P)
- Immune tab for special wash instructions performed on an **e** 601

For information on special operation procedures, see:
Programming a special wash for c 501 modules on page B-297
Programming a special wash for e 601 modules on page B-304

Chemistry screen

➔ **Utility** > **Special Wash** > **Chemistry**

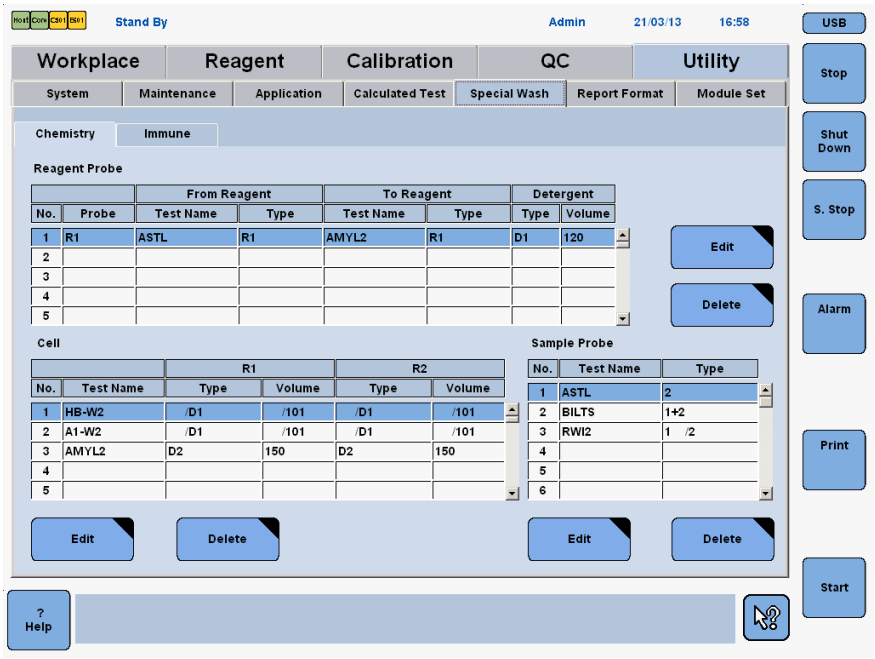


Figure E-326 Chemistry tab on Utility > Special Wash

Chemistry Use this screen to program special wash instructions for reagent probes, reaction cells and the sample probe on a **c** 501 (P).

For more information, see *Programming a special wash for c 501 modules* on page B-297.

Reagent Probe area

No. The **No.** column displays the number of the reagent probe wash. Up to 50 additional wash steps can be programmed for both reagent probes.

Probe The **Probe** column specifies the probe to be washed (**R1** or **R2**).

From Reagent Test Name The **Test Name** (**From Reagent**) column displays the test name (for example **ALB**) causing possible carryover.

From Reagent Type The **Type** (**From Reagent**) column displays the reagent type (for example **R2**) causing possible carryover.

To Reagent Test Name The **Test Name** (**To Reagent**) column displays the test name (for example **ALP**) affected by possible carryover.

To Reagent Type The **Type** (**To Reagent**) column displays the reagent type (for example **R3**) affected by possible carryover.

Detergent Type The **Type** (**Detergent**) column displays the detergent type that is used for the additional wash step.

Detergent Volume The **Volume** (**Detergent**) column displays the volume of the detergent that is used for the additional wash step.

The system will carry out the additional wash step whenever the defined pipetting order (**From Reagent To Reagent**) appears during the analysis. You must select an open number from the list to program a new wash step.

Edit Choose this button, located in the middle of the screen to the right, to add a new or to edit an existing reagent probe wash.

See *Edit Reagent Probe Wash window* on page E-532.

Delete Use this button, located in the middle of the screen to the right, to delete the probe wash selected in the **Reagent Probe** list.

Select the probe wash to be deleted from the **Reagent Probe** list, then choose **Delete** to delete the selected probe wash after confirmation.

Cell area

Use this area to view the cell wash program, to add a new cell wash program or to edit an existing cell wash. Select an unused line in the **Cell** list to add a new wash program or select an existing program to edit it.

No. The **No.** column displays the number of the cell wash. Up to 50 additional wash steps can be programmed for all reaction cells.

Test Name The **Test Name** column displays the name (for example **ALB**) of the test that could be the cause of possible carryover into the reaction cell.

R1 Type The **Type** (**R1**) column displays the detergent type used by reagent probe 1 for the additional wash step.

R1 Volume The **Volume** (**R1**) column displays the volume of detergent used by reagent probe 1 for the additional wash step.

R2 Type The **Type** (**R2**) column displays the detergent type used by reagent probe 2 for the additional wash step.

R2 Volume The **Volume** (**R2**) column displays the volume of detergent used by reagent probe 2 for the additional wash step.

The system will carry out the additional wash step for a reaction cell whenever the cell has contained any reagents used by the indicated test. You must select an open number from the list to program a new wash step.

Edit Choose this button, located at the bottom left of the screen, to add a new or to edit an existing cell wash program.

See *Edit Cell Wash window* on page E-533.

Delete Use this button, located at the bottom left of the screen, to delete the cell wash selected in the **Cell** list.

Select the cell wash to be deleted from the **Cell** list, then choose **Delete** to delete the selected cell wash after confirmation.

Sample Probe area

No. The **No.** column displays the number of the sample probe wash. Up to 50 additional wash steps can be programmed for the sample probe.

Test Name The **Test Name** column displays the test name (for example **ALB**) affected by possible carryover.

Type The **Type** column displays the detergent used for washing.

Edit Choose this button, located at the bottom right of the screen, to add a new or to edit an existing sample probe wash.

See *Edit Sample Probe Wash window* on page E-535.

Delete Use this button, located at the bottom right of the screen, to delete the probe wash selected in the **Sample Probe** list.

Select the probe wash to be deleted from the **Sample Probe** list, then choose **Delete** to delete the selected probe wash after confirmation.

Edit Reagent Probe Wash window

➔ **Utility** > **Special Wash** > **Chemistry** > **Edit** (right to **Reagent Probe** list)

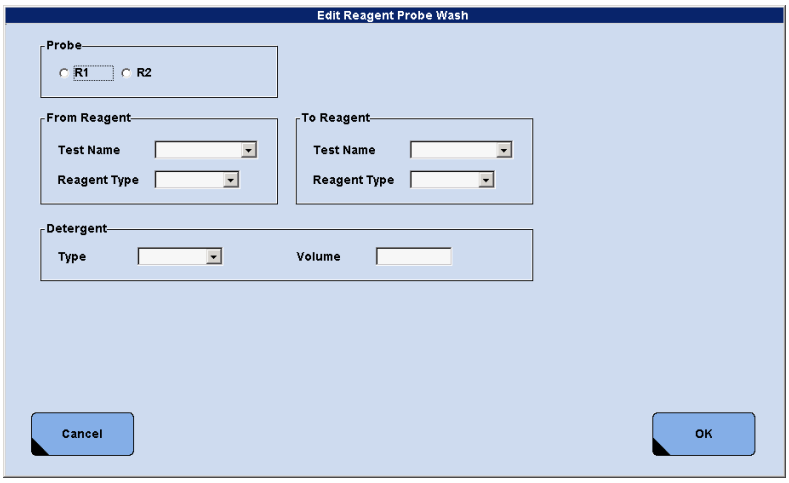


Figure E-327 Edit Reagent Probe Wash window

Use this window to add a new reagent probe wash program or to edit an existing reagent probe wash.

Probe area

R1 Select the **R1** option to perform the wash on reagent probe R1.

R2 Select the **R2** option to perform the wash on reagent probe R2.

From Reagent area

Test Name Use this list box to select the test that causes the potential carryover. An individual test or all tests can be selected.

Reagent Type Use this list box to specify which reagent type (**R1**, **R2**, or **R3**) causes the potential carryover.

To Reagent area

Test Name Use this list box to select the affected test. An individual test or all tests can be selected.

Reagent Type Use this list box to specify which reagent type (**R1**, **R2**, or **R3**) is affected by carryover.

Detergent area

Type Use this list box to specify the detergent type (**D1**, **D2, D3**, or **Water**) to be used for the additional probe wash.

Volume Use this text box to specify the volume of detergent used for the probe wash.

Edit Cell Wash window

➔ **Utility** > **Special Wash** > **Chemistry** > **Edit** (below **Cell** list)

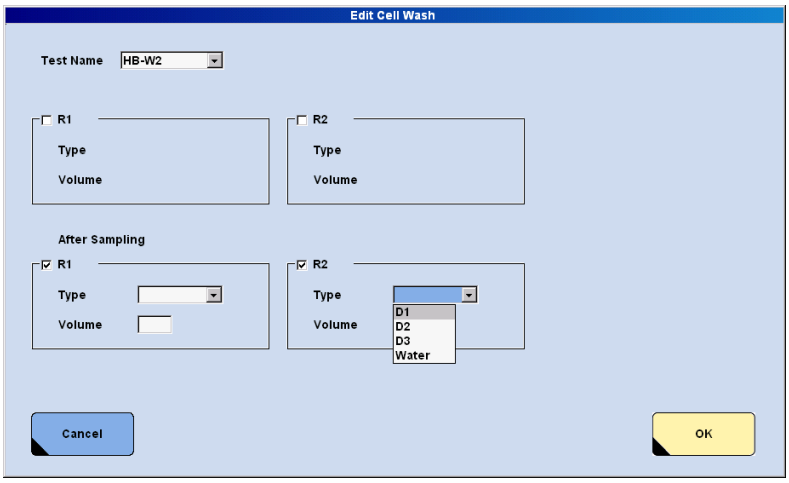


Figure E-328 Edit Cell Wash window

Use this window to add a new or to edit an existing cell wash program.

To evade the carryover of traces of the test mixture of one test to the next test measured in that same reaction cell, program a special wash cycle for the reaction cell. In this case a special wash is carried out *before* the corresponding test is performed.

For the HbA1c application (HB-W3, A1-W3) this window shows the **After Sampling** area additionally. In this area you can define special washes for the reaction cell in which the HB-W3 test or the A1-W3 test was performed. In this case a special wash is carried out *after* the corresponding test was performed.

Test Name Use this list box to specify the test that causes potential cell carryover.

R1 area

Select the **R1** check box to enable Reagent 1 for the cell wash program. If **R1** is enabled, the **Type** and **Volume** fields are activated.

If the check box is clear, **R1** is disabled for the cell wash program.

Type Use this list box to specify the type of wash solution (**D1**, **D2, D3**, or **Water**) used for **R1** in the cell wash program.

Volume Use this text box to specify the volume of wash solution used for **R1** in the cell wash program.

R2 area

Select the **R2** check box to enable Reagent 2 for the cell wash program. If **R2** is enabled, the **Type** and **Volume** fields are activated.

If the check box is clear, **R2** is disabled for the cell wash program.

Type Use this list box to specify the type of wash solution (**D1**, **D2, D3**, or **Water**) used for **R2** in the cell wash program.

Volume Use this text box to specify the volume of wash solution used for **R2** in the cell wash program.

Edit Sample Probe Wash window

➔ **Utility** > **Special Wash** > **Chemistry** > **Edit** (below **Sample Probe** list)

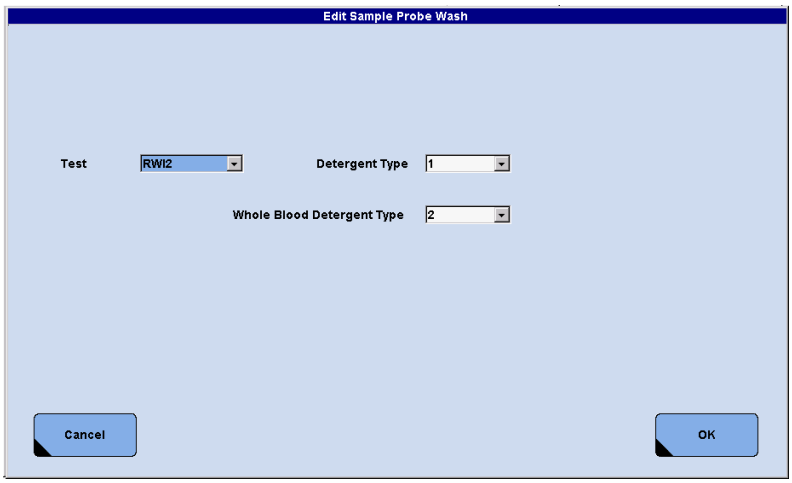


Figure E-329 Edit Sample Probe Wash window

The sample probe dips into the sample when it aspirates sample liquid. To evade a carryover of sample liquid into a test that is sensitive for sample residual, program a special wash cycle for the sample probe.

Test Use this list box to select the test that causes the potential carryover. An individual test or all tests can be selected.

Detergent Type Use this list box to select the detergent type that is used for the additional wash step.

Whole Blood Detergent Type Use this list box to select the detergent type that is used for the additional wash step. This list box is only available if a whole blood test is selected in the **Test** list box.

Immune screen

➔ **Utility** > **Special Wash** > **Immune**

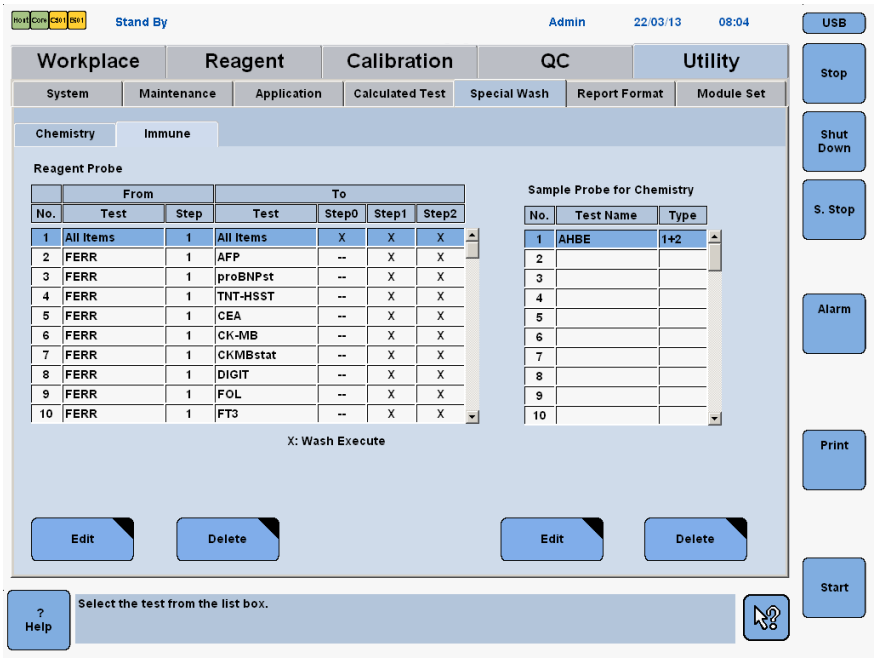


Figure E-330 Immune tab on Utility > Special Wash

Use this screen to program special wash instructions for the reagent probe on an **e** 601 or for the sample probe of the **c** 501.

In the context of **e** 601 special wash, the term *sample probe* refers to the sample probe of the **c** 501, not to the **e** 601 sample probe.

Prior to pipetting the **c** 501 test, the sample probe of the **c** 501 is washed with the specified detergent if afterwards an **e** 601 test is requested.

For more information which special wash steps should be programmed please refer to your Roche service representative.

For more information, see *Programming a special wash for e 601 modules* on page B-304.

Reagent Probe

No. This column displays the number of the programmed special wash step. A maximum of 100 special washes can be programmed.

From Test This column displays the short name of the test from which carryover could originate.

Step This column displays the reagent pipetting sequence steps (**0**, **1**, 2) of the source test (From Test) from which carryover could originate.

To Test This column displays the short name of the test to which carryover could be transferred.

Step0 This column represents the sequence step 0 of the target test (To Test) to which carryover could be transferred. If a wash is programmed prior to this step, an **X** is displayed in this column. Step 0 represents a pipetting of Pretreatment or Diluent.

Step1 This column represents the sequence step 1 of the target test (To Test) to which carryover could be transferred. If a wash is programmed prior to this step, an **X** is displayed in this column. Step 1 represents the pipetting before the first incubation.

Step2 This column represents the sequence step 2 of the target test (To Test) to which carryover could be transferred. If a wash is programmed prior to this step, an **X** is displayed in this column. Step 2 represents the pipetting before the second incubation.

Buttons

Edit Choose this button, located at the bottom left of the screen, to add a new or to edit an existing reagent probe wash.

See *Edit Reagent Probe Wash window* on page E-538.

Delete Use this button to delete a selected reagent probe wash program after confirmation.

Sample Probe for Chemistry

The **Sample Probe for Chemistry** area is only displayed if the system has a **c** 501.

No. This column displays the number of the special wash. A maximum of 100 special washes can be programmed.

Test Name This column displays the short name of the test which is affected by sample carryover from pipetting by the sample probe of the **c** 501.

Type This column displays the detergent type used for the additional rinsing of the **c** 501 sample probe.

Prior to pipetting the **c** 501 test, the sample probe of the **c** 501 is washed with the specified detergent if in addition the specified **e** 601 test is requested.

Buttons

Edit Choose this button, located at the bottom right of the screen, to add a new or to edit an existing sample probe wash for chemistry.

See *Edit Sample Carry Over Evasion window* on page E-539.

Delete Use this button to delete a selected special wash program after confirmation.

Edit Reagent Probe Wash window

➔ **Utility** > **Special Wash** > **Immune** > **Edit** (below **Reagent Probe** list)

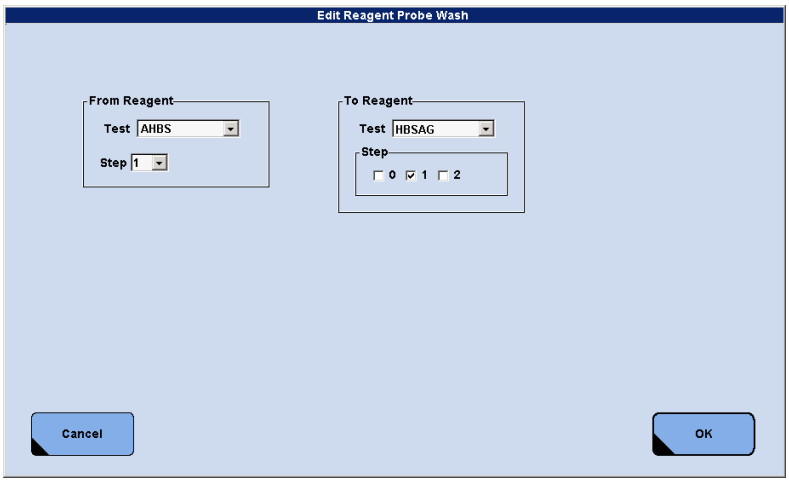


Figure E-331 Edit Reagent Probe Wash window

From Reagent

Test Use this list box to select the test that causes the potential carryover to the test which is pipetted afterwards. If you select **All Items**, the reagent probe is always washed if the selected test in the **To Reagent** area is pipetted afterwards.

Step This list box displays the reagent pipetting sequence steps (**0**, **1**, **2**) of the source test from which carryover could originate.

Step0: Pipetting step of pretreatment or diluent.

Step1: Pipetting step before the first incubation.

Step2: Pipetting step before the second incubation.

To Reagent

Test Use this list box to select the test that may be affected by the potential carryover. If you select **All Items**, the reagent probe is always washed if the selected test in the **From Reagent** area was pipetted before.

Step Use these check boxes to define for which pipetting steps the special wash has to be performed.

If, for example, for HBSAG step 1 is pipetted, and afterwards for AHBS step 1 is pipetted and you want to avoid carryover you have to program the following wash step:

From Reagent: **Test** HBSAG, **Step** 1 **To Reagent**: **Test** AHBS, **Step** 1. In case this pipetting combination occurs during operation the system will perform a wash step with ProbeWash M to avoid carryover.

Edit Sample Carry Over Evasion window

➔ **Utility** > **Special Wash** > **Immune** > **Edit** (below **Sample Probe** list)

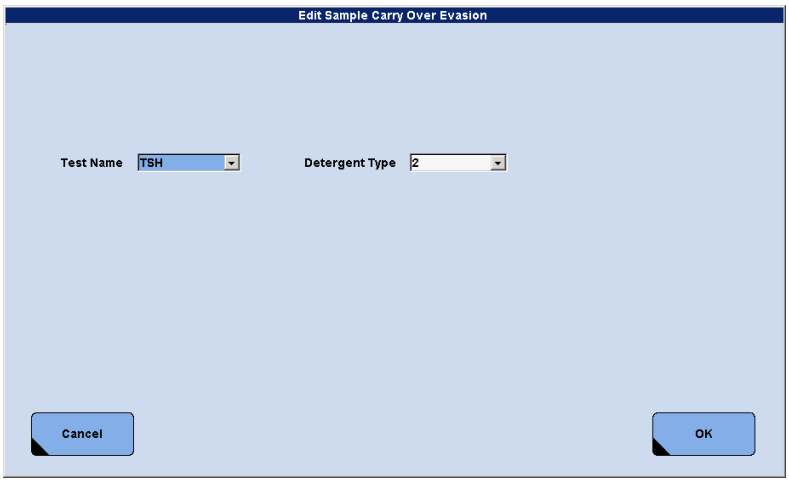


Figure E-332 Edit Sample Carry Over Evasion window

Test Name Use this list box to select the **e** 601 test that might be influenced by a potential carryover.

Detergent Type Use this list box to select the detergent type that is used for the additional wash step on the **c** 501 if a sample is processed first on the **c** 501.

If an **e** 601 test result might be influenced by samples pipetted on the **c** 501, then the test is defined as a High Priority test and a special wash step for the sample probe on **c** 501 is not necessary.

Report Format screen

➔ **Utility** > **Report Format**

This screen can be accessed by an operator with administrator level only.

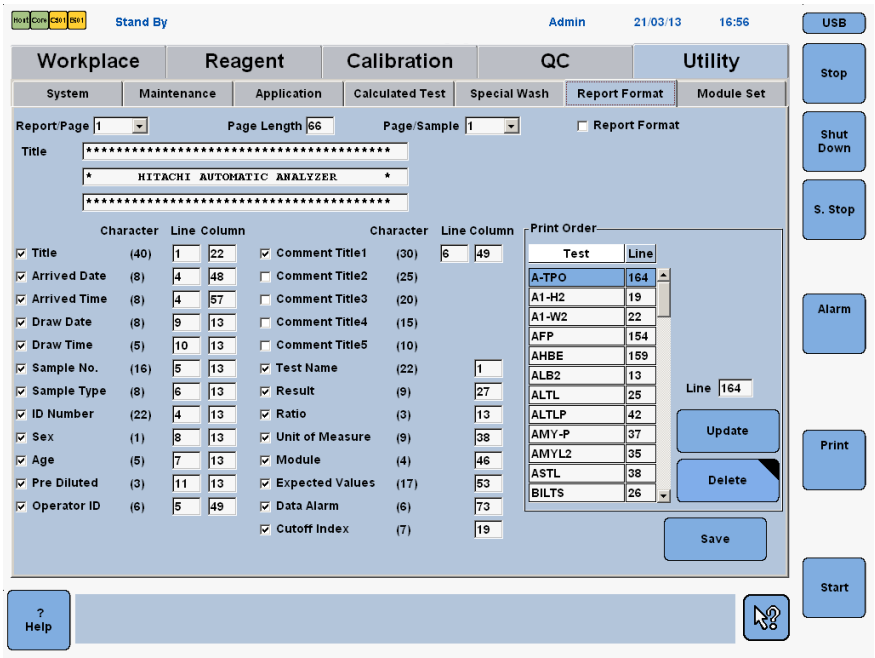


Figure E-333 Report Format screen

This screen is used to define the printing format for patient reports.

See *Customizing patient report format* on page B-306.

Report/Page Use this list box to enter the number of patients printed on each page of a report.

Page Length Use this text box to enter the number of lines in each report (5 to 72). US paper is 66 lines; A4 is 72 lines.

Page/Sample Use this list box to select the number of pages that 1 patient report will be printed on.

Report Format Select this check box to enable, or deselect it to disable printing reports in the report format.

The **Report Format** setting has an effect on the automatically printed reports only (**Utility** > **System** (**Page 4/4**) > **Auto. Printout**). If you print the reports from the **Print** screen (global button) you can select the format regardless of this setting.

For information about the automatic printout, see *Automatic Printout Setting window* on page E-418.

Results with exception data alarms (**Utility** > **System** (**Page 4/4**) > **Review By Exception**) are not printed in the report format.

For information on exception data alarms, see *Review By Exception window* on page E-419.

Title Use these 3 text boxes to enter the report title.

The title consists of up to 3 lines with a maximum of 40 characters per line and appears on every patient report.

Character Line Column list

The following fields are used to define where each of the report data is printed. Select the check box to include or deselect it to exclude the corresponding data from the report.

The number in parentheses in the **Character** column indicates the maximum number of characters for the data.

The **Line** text boxes are used to enter the line number the data is printed on. Line numbers range from 1 to the number entered in the **Page Length** text box.

The **Column** text boxes are used to define the column number where the data will begin printing on the line. Column numbers range from 1 to 80 for Report/Page 1 and from 1 to 40 for Report/Page 2.



When assigning a print column, allow for the maximum character length for the item if assigning more than 1 demographic item to the same line. For example, if the arrived date is assigned to line 4, column 47 and the arrived time is also assigned to line 4, it must be assigned to column 56 or higher since the character length for the arrived date is 8. If the second item is assigned to a column that is used by the first item, one of the items will not be printed.

Title Select this check box to include or deselect it to exclude the title.

Use the adjacent text boxes to enter the **Line** and **Column** the data will be printed on.

Arrived Date Select this check box to include or deselect it to exclude the arrived date.

Use the adjacent text boxes to enter the **Line** and **Column** the data will be printed on.

Arrived Time Select this check box to include or deselect it to exclude the arrived time.

Use the adjacent text boxes to enter the **Line** and **Column** the data will be printed on.

Draw Date Select this check box to include or deselect it to exclude the draw date.

The **Draw Date** is downloaded from the Host or can be entered manually on **Workplace** > **Test Selection** > **Demographics**.

Use the adjacent text boxes to enter the **Line** and **Column** the data will be printed on.

Draw Time Select this check box to include or deselect it to exclude the draw time.

The **Draw Time** is downloaded from the Host or can be entered manually on **Workplace** > **Test Selection** > **Demographics**.

Use the adjacent text boxes to enter the **Line** and **Column** the data will be printed on.

See *Demographics window* on page E-211.

Sample No. Select this check box to include or deselect it to exclude the sample number.

Use the adjacent text boxes to enter the **Line** and **Column** the data will be printed on.

Sample Type Select this check box to include or deselect it to exclude the sample type.
Use the adjacent text boxes to enter the **Line** and **Column** the data will be printed on.

ID Number Select this check box to include or deselect it to exclude the sample ID number.
Use the adjacent text boxes to enter the **Line** and **Column** the data will be printed on.

Sex Select this check box to include or deselect it to exclude the patient's sex.
Use the adjacent text boxes to enter the **Line** and **Column** the data will be printed on.

Age Select this check box to include or deselect it to exclude the patient's age.
Use the adjacent text boxes to enter the **Line** and **Column** the data will be printed on.

Pre Diluted Select this check box to include or deselect it to exclude pre-dilution information.
Use the adjacent text boxes to enter the **Line** and **Column** the data will be printed on.

Operator ID Select this check box to include or deselect it to exclude the operator ID.
Use the adjacent text boxes to enter the **Line** and **Column** the data will be printed on.

Comment Title 1 through 5 Select this check box to include or deselect it to exclude the comments.
Use the adjacent text boxes to enter the **Line** and **Column** the data will be printed on.



The comment titles are defined on the **Utility** > **System** (**Page 1/4**) > **Comment**. Your comment titles may be different than the examples shown here.

Test Name Select this check box to include or deselect it to exclude the test name.
Use the adjacent text box to enter the **Column** the data will be printed on.

Result Select this check box to include or deselect it to exclude the test result.
Use the adjacent text box to enter the **Column** the data will be printed on.

Ratio Select this check box to include or deselect it to exclude ratio information.
Use the adjacent text box to enter the **Column** the data will be printed on.

Unit of Measure Select this check box to include or deselect it to exclude the measurement unit.
Use the adjacent text box to enter the **Column** the data will be printed on.

Module Select this check box to include or deselect it to exclude the analytical module on which the test was performed.
Use the adjacent text box to enter the **Column** the data will be printed on.

Expected Values Select this check box to include or deselect it to exclude the expected values.
Use the adjacent text box to enter the **Column** the data will be printed on.

Data Alarm Select this check box to include or deselect it to exclude any data alarm.
Use the adjacent text box to enter the **Column** the data will be printed on.

Cutoff Index Select this check box to include or deselect it to exclude the cutoff index.
Use the adjacent text box to enter the **Column** the data will be printed on.

Print Order area

Test list, Test column The **Test** column displays all tests programmed on the system.

Test list, Line column The **Line** column displays the programmed print line for each test. The line number represents the order in which test results appear on the report.

Line Use this text box to define the print line (print order) of the selected test on the patient report.

Update Choose this button to update the **Line** column in the test list.

Delete Choose this button to delete a print line assignment from the selected test in the test list.

Module Set screen

➔ **Utility** > **Module Set**

This screen can be accessed by an operator with administrator level only.

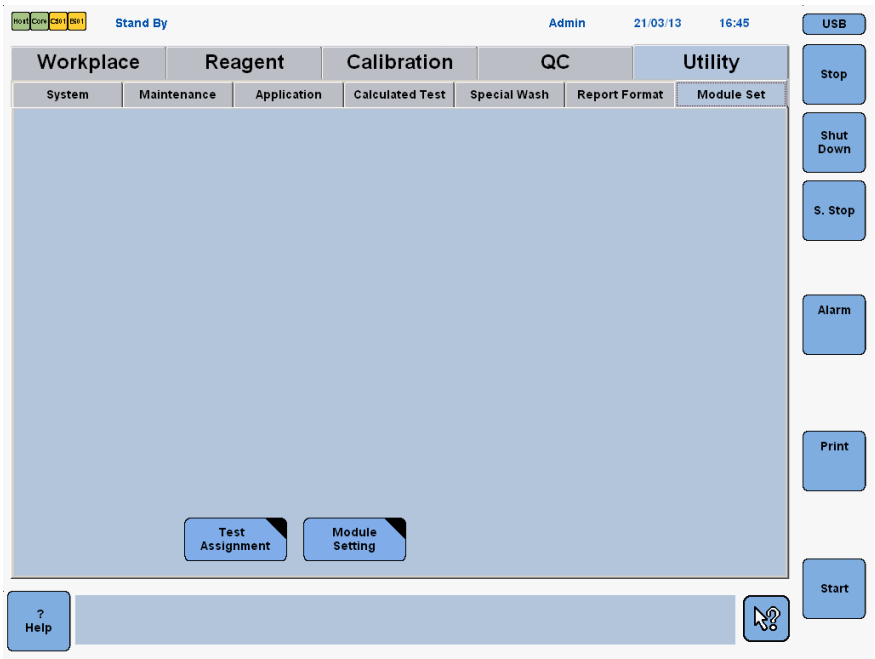


Figure E-334 Module Set screen

This screen is used to access the **Test Assignment** and **Module Setting** windows.

For information on special operation procedures, see:
Assigning a test to a module on page B-288
Inactivating a module on page B-290

Test Assignment Choose this button to specify which tests are performed on which modules.

See *Test Assignment* on page E-545.

Module Setting Choose this button to activate or deactivate modules.

See *Module Setting* on page E-549.

Test Assignment

➔ **Utility** > **Module Set** > **Test Assignment**

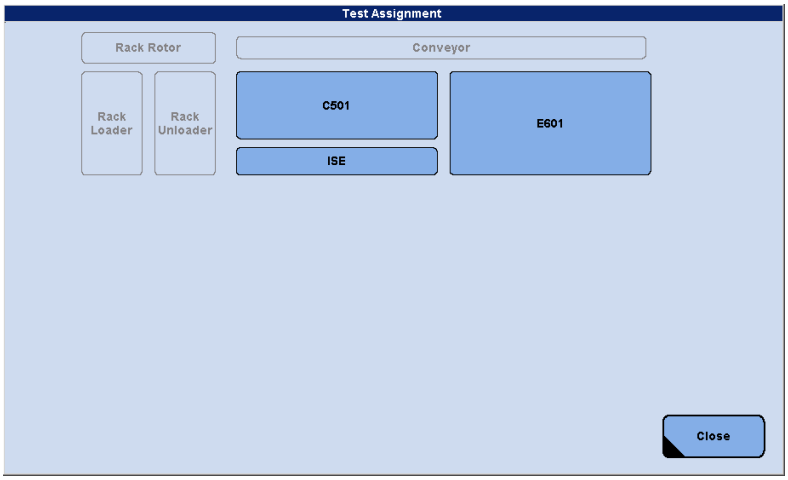


Figure E-335 Test Assignment window

This window is used to specify which tests are performed on which modules. It displays a system layout.

***c** 501 / **e** 601* Select a module button to open the respective **Module Test Assignment** window.

c501 Test Assignment(C Module)

➔ **Utility** > **Module Set** > **Test Assignment** > **c** 501

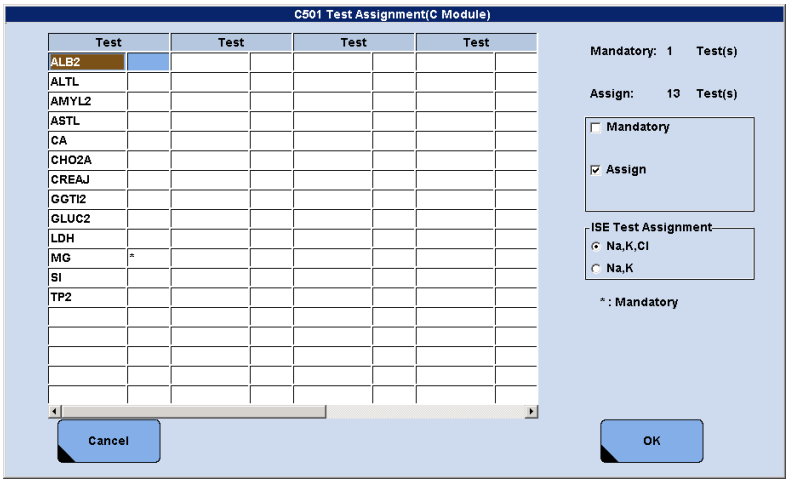


Figure E-336 c501Test Assignment(C Module) window

This window is used to assign tests to the selected **c** 501.

Test list This list displays all tests available on the system that can be performed by a **c** 501 (P). If a test is not assigned to any of the detection channels of the selected module, it appears disabled (grayed out). Mandatory tests are marked with an asterisk (*).

Use this list to select a test and assign or unassign it to the selected **c** 501 (P).

Mandatory This field displays the total number of tests defined as mandatory for the selected module.

Assign This field displays the number of assigned tests to the selected module.

Mandatory Select this check box to define the test selected in the test list as mandatory for the selected module.

Assign Clear this check box to remove a selected test from the selected module. Select this check box to assign an unavailable (grayed out) test for the selected module.

If a test assignment is removed from any module while the **cobas c** pack is on board, the corresponding **cobas c** pack is displayed with question marks (**????**) on the **Reagent Status** list.

Na,K,Cl Select the **Na,K,Cl** option to allow sodium ($\mathbf{Na^+}$), potassium ($\mathbf{K^+}$), and chloride ($\mathbf{Cl^-}$) ion testing on the **c** 501 (ISE).

Na, K Select the **Na,K** option to allow only sodium ($\mathbf{Na^+}$) and potassium ($\mathbf{K^+}$) testing on the **c** 501 (ISE).

Mandatory Mandatory tests are marked with an asterisk (*) in the test list.

e601 Test Assignment(E Module)

➔ **Utility** > **Module Set** > **Test Assignment** > **e** 601

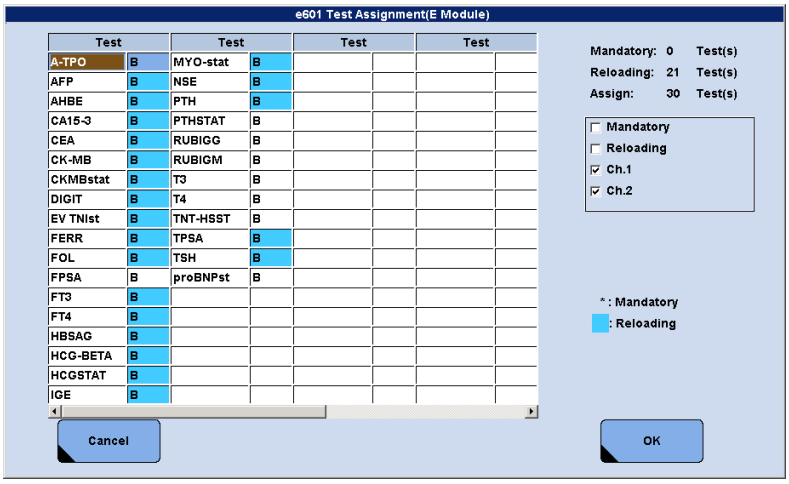


Figure E-337 **e**601 Test Assignment(E Module) window

Use this window to assign tests to the selected module and measuring channel.

Test list

This list displays all installed applications on the system together with the measuring channel to which they are assigned (**1** for channel 1, **2** for channel 2 and **B** for both channels). Mandatory tests are marked with an asterisk (*) and reloading tests are highlighted with a blue background.

If a test is not assigned to any of the channels of the selected module, it appears disabled (grayed out). If a test assignment is removed from any module and measuring channel, the corresponding **cobas e** pack is displayed with question marks (**????**) on the **Reagent Status** screen.

Use this list to select a test and assign it to one or both measuring channels of the selected module.

Mandatory

This field displays the total number of tests defined as mandatory for the selected module.

Reloading

This field displays the total number of tests defined for reloading for the selected module.

Assign

This field displays the number of assigned tests to the selected module.

Mandatory

Select this check box to define the test selected in the test list as mandatory for the selected module.

Reloading Select this check box to define the test for reloading on the selected module. A module will go into standby when the remaining tests for this test is "0".

- The reagents necessary for a test defined as mandatory must be loaded on the system otherwise the system will not start.
- Whether the **Preventive Action** check box is selected on the **System Overview** screen or not has no influence for mandatory tests.

Ch. 1 Select this check box to assign the test to measuring channel 1 of the selected module.

Ch. 2 Select this check box to assign the test to measuring channel 2 of the selected module.

Mandatory Mandatory tests are marked with an asterisk (*) in the test list.

Reloading Reloading tests are highlighted with a blue background in the test list.

Module Setting

➔ **Utility** > **Module Set** > **Module Setting**

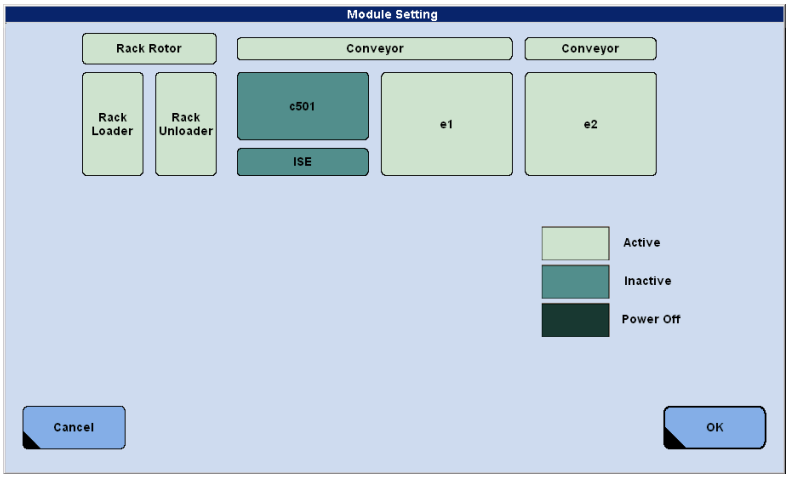


Figure E-338 Module Setting window

This window is used to activate/deactivate modules.

The window displays a system layout diagram. Choosing a module changes its state successively from **Active**, to **Inactive**, to **Power OFF**, and back. The current status of the module is shown by different colors explained on the window.

Glossary F

Glossary

This glossary is a compendium in which to look up the meaning of technical terms used in conjunction with the **cobas** 6000 analyzer series.

Numbers

2-dimensional barcode A type of barcode on **cobas e** packs, calibrators, and control barcode cards or sheets. These matrix barcodes, which use PDF417 symbology, contain more information than traditional linear barcodes.

A

absorbance (Abs) The instrument displays an absorbance by ten-thousandfold value.

aspiration station A position on the **e** 601 module located next to the incubator where an AssayCup containing the reaction mixture is placed for aspiration into the measuring cell by the sipper probe.

assay 1. A specific test.
2. The process of measuring a substance.

AssayCup A plastic vessel that is used to hold the assay reaction mixture. An alternative term is reaction vessel.

AssayTip A disposable pipette tip made of black, conductive plastic. AssayTips are used by the sample probe.

assigned value (Roche-defined) Roche-defined concentration for calibrator material that is encoded on the calibrator barcode card or e-barcode. See also *target value*.

automatic calibration 1. Automatic timeout calibration. A calibration of a parameter performed if a specified time interval expires. The calibration can be defined for each method separately.
2. Automatic calibration after a cassette or a cassette of a new lot is registered. The calibration can be defined for each method separately.
3. Automatic calibration on QC failure. A calibration request is generated by the system if a QC value is outside a predefined range.

Automated Download (ADL) A service that provides the information necessary for analysis, for example analytical parameters or concentration information from the data center. ADL is a cobas TeleService application. See also *cobas TeleService*.

automatic QC A quality-control function that automatically samples QC material, test-specifically according to defined time intervals.

automatic rerun The repetition, without operator intervention, of tests that have results with data alarms.

auxiliary reagent A non-test specific reagent that is needed to perform testing on an analyzer.

B

backup 1. The saving of data onto supplementary storage media such as disks or DVDs. If such data is required but is no longer available from the main storage (instrument database), it can be restored from a backup copy.
2. An internal instrument-specific process to establish the data for a backup; only used in a case of routine instrument break down.

backup operation A software function that allows to place routine racks with barcoded samples manually on the **c** 501 module. Intended to be used when trouble occurs in the rack sampler and a rack cannot be conveyed.

barcode mode The operational mode when a system is configured to operate using barcoded samples.

barcode type Typical sample barcode types used in the IVD industry are Code39, NW7 (Codabar), ITF, and Code 128.

bichromatic measurement The measured absorbance of the primary wavelength and the secondary wavelength.

blank cell Calibration procedure for ECL instruments performed by Roche service representative.

bound/free separation The physical separation of reagent or sample that is bound to a solid phase (the microbeads) from free reagent or sample. With ECL systems this step occurs in the measuring cell.

Bracketing A mode of operation in which patient results have to be surrounded by successful control results before they are released.

bridging principle One of three test principles that can be applied to ECL immunoassays. It is used to detect antibodies (such as IgG, IgM, or IgA) in the sample. See also *competitive principle*, *sandwich principle*.

C

calculated result See calculated test.

calculated test A test result calculated from different individual analytical methods with a given formula such as ratio A/B.

calibration The process that establishes the relation between measured signals (e.g. from a photometer, photomultiplier, or ion-selective electrodes) and corresponding concentration values of a calibrator.

calibration curve A plot of measured signal values (determined during calibration) versus known concentration values of calibrators.

calibration factor 1. In ECL systems (**e** 601), one of the six calibration quality criteria used to verify the validity of a calibration. This criterion is only used for reagent pack calibrations. It is derived by comparing two different calibrations. A factor of 1.0 is achieved when two calibrations are equal. A successful calibration has a factor of 0.8-1.2.
2. In photometric systems (**c** 501) the K factor and S1Abs (linear calibration), and factors A, B, C for non-linear calibration curves.

calibration frequency A specified interval at which an assay should be calibrated. Also referred to as calibration stability. It is implemented in the application parameters which are downloaded via **cobas** link or encoded in the reagent barcode of cobas e packs.

calibration function The type of calibration (for example, Rodbard function, linear function, or cutoff function). A mathematical model that describes the relationship between a signal and a concentration in the calibration curve. See calibration curve.

calibration masking A function that masks a **cobas c** pack or **cobas e** pack for a module or measuring channel when no valid calibration is available for this particular module or measuring channel.

calibration monitor A function that prints the measured absorbance of the standard solution and the calibration factors, at the time of calibration, for every measurement item.

calibration NOW A system-generated recommendation to carry out calibration within a forthcoming defined time interval (Remaining time on **Calibration** > **Status** screen).

calibration quality criteria Calibration checks applied to the auto-validation of every calibration on the analyzer.

calibration trace A graph used to review the measurements of the 50 most recent calibrations for a specific test.

calibration type 1. In clinical chemistry: One of the following: Linear, RCM, RCM2T1, RCM2T2, Spline, Line Graph. Each calibration type corresponds to one specific type of mathematical function. See calibration function.
2. For ECL systems: Lot calibration (L-Cal) or reagent pack calibration (R-Cal).
3. In clinical chemistry: Lot calibration or cassette calibration.

calibration validation Analysis, performed by software, to check a calibration data set against specific criteria. Calibration validation results are: successful or failed.

calibration verification The assaying of calibration materials in the same manner as patient samples to confirm that the calibration of the instrument kit or test system has remained stable throughout the laboratory's reportable range for patient test results (for example, Elecsys CalChecks).

calibrator A material of known concentration of the parameter that can be presented to the analytical instrument for calibration purposes. Also referred to as standard.

calibrator code The identification number of the standard solution in calibration measurement.

capacitance An electrical property that provides the basis for liquid level detection in sample probes. The probes carry a high-frequency, low-voltage electrical charge. Frequency and electrical charge characteristics are altered and sensed when the probe touches liquid.

carryover Contamination of a reaction mixture of one assay by reagents or sample material of another assay.

cassette The integrated reagent carrier consisting of two or three reagent bottles and barcoded labels. The term cassette, on cobas systems, is related to different reagent carriers, namely INTEGRA cassettes, **cobas c** packs, or **cobas c** pack MULTI.

cell blank The process of measuring the absorbance of all reaction cells, filled with water, at all wavelengths. The cell blank values are stored on the database. By periodic cell blank measurement, reaction cells can be screened for contamination or damage.

cell holder A container holding the electrode in the electrode measurement unit.

cell rinse units A device for cleaning the reaction cells with detergent and water and for dispensing and aspirating cell blank water.

channel 1. The number of reagent positions on an analytical instrument.
2. A specific reagent position.
3. The two measuring cells on the **e** 601 are sometimes referred to as channel one and channel two.

check digit A verification number used in barcodes and software.

check sum The result of a mathematical procedure to validate the integrity of a set of data.

circuit breaker The main power switch on the instrument. It controls the power supply including the power to the Peltier elements. Consequently it controls the temperature in each reagent disk, incubator, and detection unit.

cleaning solution See wash solution.

client/server A network in which computer processing is distributed among many individual PCs (clients) and a more powerful, central computer (server).

clot detection 1. A device built into the pipetting system to detect clots and to avoid false pipetting.
2. The procedure of detecting a clot.

cobas® The "umbrella brand name" for a broad range of products and services for use in professional IVD laboratories and physician's office settings.

cobas c pack The name given to a reagent cassette used on **cobas c** systems and COBAS INTEGRA® systems.

cobas c pack MULTI The name given to an empty, but assembled and barcoded, cassette that can be used for Roche or Non-Roche reagents. The word multi in this name stands for multi-purpose.

cobas e pack The name given to a reagent pack used on cobas e systems and Elecsys® systems.

cobas link The infrastructure of network connections that enables cobas TeleService to exchange information between the Roche service network and a customer's laboratory.

cobas link PC A specific desktop computer, located in the laboratory, that has been configured to act as a gateway between Roche systems and the Internet. As well as providing a communication link, the **cobas** link PC also stores data and documentation for assay processing and can provide a data archive.

cobas TeleService The set of software applications that use **cobas** link to exchange service information between Roche service network and a customer's laboratory. cobas TeleService provides remote monitoring and diagnosis, hotline support, and software and documentation updates.

Code39 A barcode type for sample tubes that can be read by the barcode reader.

coefficient of variation A statistical measure used to describe imprecision. Often abbreviated to CV.

compensated test A test that has the result modified by a formula that takes account of known or defined interference factors.

competitive principle One of three test principles that can be applied to ECL immunoassays. It is used to detect analytes of low molecular weight (for example, FT3). See also *bridging principle*, *sandwich principle*.

conditioning The process of letting serum-type liquid flow through the flow path before electrolyte measurement.

consumables A generic term for items that are used during test processing and must be replaced on a regular basis by the operator. Examples of consumables include AssayCups, printer paper, and reaction cells.

consumables area The area of an analyzer where the consumables, such as AssayCups and AssayTips, are stored.

continuous loading/access Instrument function that allows loading of samples and reagents during operation.

control ID The abbreviated name for a control material, for example PC U1 or PC TSH. Control IDs are used on software screens and windows where limited space prevents the use of longer names.

control material A material used to assess the performance of an analytical procedure or part of an analytical procedure. Also called the control sample.

control name The name of a control material, for example PreciControl Universal.

control SD value The acceptable variation SD value of a quality control sample.

control unit An external PC or printer by which an analytical system is controlled. The control unit also serves as the user interface.

core unit The backbone of modular instruments for sample transportation.

correction item A function that corrects the measurement result of one item by using figures or the measurement result of other tests.

cumulative QC The accumulated data and associated statistics of individual QC data.

cup disposal opening Openings where used AssayCups are disposed into the solid waste.

cup-on-tube The placement of a smaller secondary sample container (for example a Hitachi Cup) on top of a primary sample tube

cycle The instrument time interval during which pipetting or measurement can be carried out.

cyclic QC Controls run at fixed intervals.

D

data alarm Printed or displayed notification that occurs if a result (including calibration or QC results) is unexpected or abnormal; an indication of unusual reaction or instrument conditions, for example, insufficient sample or reagent.

data flag See data alarm.

database A defined section of the computer memory where all instrument, assay, and patient-relevant data are processed and stored.

database management system A software system that provides the necessary procedures and programs to collect, create, organize, store, retrieve, and maintain databases or data files with security and integrity.

dead volume See minimum sample volume.

default profile A predefined set of tests that the analyzer automatically applies to a sample unless the operator specifies a different set of tests.

demographics Patient-related data such as name, date of birth, and gender.

detection unit A hardware unit comprising a photomultiplier tube, Peltier elements, flow-through measuring cell, magnet drive assembly, and an amplifier circuit board.

deviation of duplicate measurements See duplicate limit.

Diagnostics The status that is required to perform system diagnostics and hardware error tracking actions. The field service engineer may request a system to go to Diagnostics mode to perform such procedures. The system may require initialization afterwards to resume normal operation.

dilute waste solution A waste solution resulting after rinsing with water.

dilution factor A software preset or manually assigned dilution ratio that is used by the analyzer to perform a requested dilution.

disk position A dedicated position on the reagent or sample disk.

down time The period of non-operation between an instrument failure and the resumption of operation.

dual value method A mode of expression of the control chart in real-time quality control. For X-axis and Y-axis, measure simultaneously the average and the standard deviation of control of a low value and a high value, and display them by X and Y coordinates, respectively.

duplicate limit A calibration quality criterion. For a successful calibration, duplicate measurements must be within a specified limit.

dynamic range The reportable range of an assay. This range extends from the lower detection limit to the limit of linearity.

E

EcoTergent 1. A detergent, with antibacterial properties, that can be added to the incubator bath where it acts as a surfactant, reducing the formation of foam. 2. A surfactant diluted for use in some cleaning procedures.

electromotive force (EMF) The physical principle that provides the basis for electrolyte measurement.

emergency stop An instrument alarm level that immediately stops all instrument functions.

endpoint assay An analytical technique taking measurements after a reaction is completed or has been halted. See also *rate assay*.

error handling A process during which the analyzer attempts to recover from an error condition (for example, an AssayTip is not picked up from the magazine). If the analyzer cannot successfully recover from error, an alarm is issued and the instrument is halted.

E-stopped A status indicating that the system has performed an emergency stop (**E. Stop**). This could be due to hardware failure or because any of the safety devices have requested an emergency stop. The system requires either complete power off, or at least initialization, to resume normal operation.

expected range The predefined range of test result values expected for a defined group of healthy patients or materials. Also known as "reference" range.

expected value A value for a test result that can be considered as a "normal" result.

expiration date Also called the expiry date. The end of a period until which Roche Diagnostics guarantees product claims for its reagents, calibrators, and controls.

extended dynamic range The measuring range for an assay at its highest dilution.

F

filter A process that sorts data for viewing, documenting, or printing according to pre-defined criteria

first registration The date and time when a reagent or sample was successfully recognized by the barcode reader for the very first time

functional sensitivity The concentration of an analyte at which a predefined level of imprecision is obtained.

G

global button A button that allows access to the global software screens and that can be used at any time.

gripper A technical device that transports AssayCups and AssayTips to their required destination on the analyzer (for example, to the incubator). The gripper moves in three directions (X, Y, and Z).

H

hard disk (HD) A computer component on which data can be written, stored, and retrieved by the means of magnetization.

Hitergent See EcoTergent.

homogeneous immunoassay (HIA) An analytical technique employing antigens and antibodies. An HIA uses assay protocols similar to clinical chemistry without a bound-free separation (for example, latex assays).

Host computer 1. A computer used for overall management and control of the computer network. 2. A clinical laboratory computer that stores and processes patient requests and results. A Host is able to communicate with analytical instruments.

Host communication Data exchange with a clinical laboratory information system (LIS).

Host interface protocol A technical description that defines data transfer between a Host computer and an analytical system.

I

ID reader Typically an optical device that reads the identification code of a patient sample or sample rack (ID) and transfers it to the instrument database.

increased volume rerun A rerun performed after increasing the amount of sample used for the determination.

incubator bath A temperature-controlled, water-filled reservoir that surrounds the reaction cells and keeps the reaction cells at a defined temperature (37°C).

incubator A temperature-controlled aluminum block for AssayCups on cobas and Elecsys instruments.

initial BlankCell procedure The calibration procedure for ECL instruments performed by Roche service representative when setting up an ECL-based analyzer for the first time.

Initialization The operational mode of an analyzer that occurs immediately after power on and during which the instrument prepares itself for operation.

input buffer A section of an analyzer where samples are loaded by using a rack or rack tray. See also *rack loader*.

instrument alarm A displayed alarm that indicates an unusual instrument condition such as an abnormal incubator bath temperature or a mechanical malfunction.

Instrument Manager Typically, PC-based software that controls or supervises one or more analytical instruments.

internal reference solution An internal standard solution, assayed between every ISE sample, that compensates for electronic drift.

inventory control The real-time monitoring of the quantities of all consumable items (liquid and solid) on an analyzer.

ISE check A maintenance function for checking whether electrolyte analysis can be performed correctly.

ISE prime A procedure that fills the ISE reagent lines and syringes with reagent.

K

K factor The reciprocal value of the slope of the calibration curve. A factor used in conversion of absorbance values to concentration values or activities.

L

linear barcode A conventional one-dimensional barcode with limited data capacity.

liquid level detection (LLD) The ability of an analytical instrument to sense liquid by using the sample or reagent probes.

liquid waste container A reservoir for liquid waste generated by an analyzer; its size and location vary between instruments.

loader See rack loader.

loading capacity The maximum number of samples that can be loaded onto the input buffer.

local area network (LAN) A computer network covering a limited area, such as an office or a home.

log file A set of data, typically stored in the control unit, that traces instrument-related or operator-related activities such as maintenance.

lot calibration (L-cal) A calibration when a new lot of reagents is introduced to an analytical instrument and calibrated within 24 hours.

M

maintenance item A maintenance procedure performed by the system or the operator.

maintenance key A button for position movement, used for a probe position check.

maintenance pipe A combination of sequential maintenance items programmed into a fully automated procedure, which can be performed by the analyzer without operator intervention.

maintenance procedure A procedure that must be performed on a regular basis (for example daily, weekly, monthly, or every three months) to secure reliable operation of the analyzer.

manual dilution An off-system, preanalytical step performed by laboratory staff to reduce the analyte concentration in a sample.

manual rerun A retest function. Although a list of samples required for a rerun is created by following data alarms, rerun is not carried out automatically. After organizing the rerun sample list, the operator directs the rerun.

masking A function that temporarily suspends the measurement or calibration of a specific test, depending on the condition of the instrument or reagent. Tests can be masked completely, or just for individual modules or channels. There are two possibilities to mask a test: If T-mask is selected, no patient samples, no controls, and no calibrations can be performed. If P-mask is selected, the test is masked for patient samples only—calibration and QC can be performed. Masking can also be applied to entire modules (module masking) so maintenance can be performed on the masked module while the other modules are still processing samples.

master calibration A reference standardization that uses master test kit reagents and certified reference standard material (for example, World Health Organization reference material) measured at Roche Diagnostics. The resulting reference standard curve, typically using 10 to 12 points, is the basis for the production of in-house master calibrators.

master curve A lot-specific master calibration curve (n=5 or 6) measured at Roche Diagnostics using lot-specific test-kit reagents and master calibrators. The shape of the lot-specific master curve is characterized by a four-parameter Rodbard function. The data characterizing this curve is stored in the lot-specific reagent barcode. Lot-specific, calibrator-assigned values (CalSet-assigned values) are read from the lot-specific master calibration curve and encoded in the CalSet calibrator barcode transfer sheet.

Material Safety Data Sheets Documents that list components of chemical solutions and precautions for the handling and disposal of the solutions.

measuring point Time at which absorbance reading is taken and used to calculate results.

measuring cell A flow-through device that is used to generate light during the ECL detection process.

measuring channel The entire pathway that is passed by the reaction mixture during the ECL measuring cycle (including tubing, heat pipe, measuring cell, photo multiplier, and so on).

measuring range See reportable range.

message In computing, a defined set of alphanumeric data that transfers information from computer to computer or from an analytical instrument to the operator.

microbead Paramagnetic streptavidin-coated microparticles used as the solid phase for heterogeneous immunoassays in ECL systems.

Microcup A secondary sample cup made by Hitachi with a small dead (residual) volume

microbead mixer A paddle or propeller that thoroughly mixes the microbead reagent to ensure resuspension before use.

minimum sample volume The amount of residual sample material plus the volume required for assaying all requested tests to ensure faultless sample aspiration.

minimum signal In ECL assays, a calibration quality criterion. A predefined, assay-specific signal level that must be achieved to establish a valid calibration.

missing value In ECL assays, a calibration quality criterion. All calibrator values must be available for a successful calibration.

mode Defined states of operation of an analyzer.

module An analytical unit that can be combined with others to form larger systems.

monotony of curve A calibration quality criterion. All measured calibrator values must fall in either ascending (sandwich or bridging principle) or descending (competition principle) order for a successful calibration.

multi-wavelength spectrophotometer A spectrophotometer in which detectors are placed at multi-wavelength positions to enable simultaneous light reception.

N

non-barcode mode A mode of instrument operation during which the instrument identifies samples by using the rack and position numbers.

O

on board 1. A technical device or function that is part of the analytical instrument and can be used by the instrument at any time.
2. The availability of reagents and consumables on an analytical instrument for use at any time.

one-way serial processing Sample flow and processing along a single, serial process lane that allows no bypass function and no rerun.

Online Help On-screen documentation that a user can request in a context-sensitive manner and search for any given term.

online support A service that supports the preparation for analysis and maintenance management by exchanging information over networks. See also *cobas TeleService*.

open request An ordered test that has not yet been performed or completed. Results for a sample may be partially available while some tests are not yet completed.

Operate The operational mode during which the instrument processes samples.

operator ID An alphanumeric ID that a system uses to identify a particular operator. There are several levels including operator, supervisor, and administrator.

order Also called a request. A test selected for a specific sample or control.

order date/time A field used to maintain the arrival date and time of an order in the laboratory. The date/time data may be entered manually or transmitted by LIS protocols.

order ID The sample order identification refers to a number of sample tubes (one or more specimen types) of a given patient collected for a panel of different tests. Typically, the sample order identification is printed on order sheets.

output buffer A section of an analyzer to which samples are moved on completion of the analytical process and from which they can be unloaded. See also *rack unloader*.

P

P-mask See Patient mask.

paramagnetic A property of materials that do not exhibit magnetic forces themselves but are capable of becoming magnetic in the presence of a magnetic field. Magnetic property of microbeads used with ECL technology.

patient ID A set of alphanumeric data that unmistakably identifies a particular patient. For example, a social security number and a sample number.

Patient mask There are two possibilities to mask a test: Test mask (T-mask) and Patient mask (P-mask). If T-mask is selected, no patient samples, no controls, and no calibrations can be performed. If P-mask is selected, the test is masked for patient samples only—calibration and QC can be performed.

pending requests See open request.

photometer A device that measures the intensity of light.

photometric assay An assay in which analytes are measured by a photometer.

photometric window A window that enables light to pass from the light source lamp and into the incubator bath.

photomultiplier A light-sensitive tube that collects and amplifies emitted photons from the ECL reaction and converts them into an electric signal.

photon A quantum of electromagnetic energy, having both particle and wave behavior, that carries the light emitted from the ECL reaction.

pinch valve A valve that pinches the suction tube and switches the flow path.

piercer A punch on the reagent transfer arm that pierces the reagent bottle seals during cassette preparation.

pipe See maintenance pipe.

pipetter A device used for pipetting (aspirating and dispensing) a fixed amount of sample or reagent from a sample or reagent container to reaction vessel.

plunger A rod that connects with the drive arm and moves up or down, depending on the pipetting amount.

post-analytical The sample management process, typically storage and archiving, after results have been reported.

potentiometric assay An assay in which analytes (for example Na, K, or Cl) are measured in millivolts by ion-selective electrodes.

Power Up The system status while it is loading programs, performing self-checks, and so on.

pre-analytical The sample management process before the analytical phase. Preanalytical processing typically involves actions such as sorting and aliquoting.

precision The closeness of agreement between independent test results obtained under prescribed conditions.

PreClean A phosphate buffer used to wash and resuspend the microbeads during the pre-wash step.

pre-dilution A dilution step performed before samples are analytically processed on the analyzer.

preventive action A series of actions, suggested by the system, that the operator should perform before daily operation to ensure sufficient inventory during the day (for example, the replenishment of reagents and consumables).

Pre-wash dispenser A technical device that dispenses PreClean into the AssayCups in the Pre-wash station.

Pre-wash sipper Sipper of the PreClean station, which aspirates reaction mixture and PreClean solution from AssayCups.

primary tube The original tube containing the sample that has been drawn from the patient.

ProbeWash An auxiliary reagent used to wash the reagent probe during special wash steps.

ProCell An auxiliary reagent that transports the reaction mixture from an AssayCup into the measuring cell and aids the ECL detection technology.

processing lane The section of an analytical module where sample racks are moved for pipetting.

profile A user-defined set of test requests.

protocol 1. A convention or standard that controls or enables the connection, communication, and data transfer between two computing end points. Protocols can be implemented by hardware, software, or a combination of the two.
2. A set of rules that guides how an activity should be performed.

prozone The antigen/antibody complex formation is predictable as long as an excess of reagent (antibody) exists. However, in patient samples with very high levels of antigen, the reaction may begin to reverse (deagglutination) because of the effect of the excess antigen. This is called a prozone effect, and without checking for this phenomenon, abnormally high samples may give incorrect or even false normal results. There are two prozone check methods available: Antigen readdition method and reaction rate method.

Q

QC error An alarm generated in realtime QC when either a low value or a high value exceeds the limit of 3SD (QC error 1) or 2.5 SD (QC error 2).

qualitative assay An assay that does not allow the determination of the concentration of an analyte, but yields a classification of the sample, such as reactive/nonreactive or positive/negative, with regard to a certain analyte.

quantitative assay An assay that allows the determination of the quantity (concentration or activity) of an analyte.

query download A communication process between instrument PC and LIS by which a predefined data set is transmitted upon request of the analytical instrument.

R

rack A sample carrier device that holds sample cups or primary sample tubes (including those for routine samples, standard and washing solutions, quality control, STAT, and rerun samples). The rack enables easy transportation on analytical systems and modules. Different rack types can be distinguished by their differing colors.

rack ID A barcode (one-dimensional or binary) at the end of the rack that unmistakably identifies the rack.

rack loader Area where the sample racks to be measured are set. 15 racks can be placed on the rack tray and 15 racks on the input buffer.

rack pusher arm An arm, located on the loader, for pushing racks.

rack rotor A device that performs the rotation movement of the sample rack from the rack feed unit, or STAT sample inlet, to the conveyance position on the sample line. The structure can hold up to twenty racks waiting for rerun or for automatic QC.

rack tray A device for carrying and handling racks. It holds up to 15 racks and is placed directly in the rack loader or unloader of the analyzer.

rack unloader Area that holds the sample racks whose measurements have completed. Fifteen racks can be stored on the rack tray and 15 racks on the output buffer.

random access The ability of an analytical instrument to process requests from a patient sample in any order.

rate assay A determination in which measurements are taken as the reaction proceeds. The rate of the reaction is proportional to the sample component being analyzed. Also known as a kinetic assay.

raw data The unprocessed values obtained during the analytical process on an instrument (for example mVolt or absorbance).

reaction bath See also *incubator bath*.

reaction cell A plastic cuvette into which sample and reagents are pipetted for the chemical or immunological reactions.

reaction disk A rotatable disk that holds the reusable reaction cells used for photometric measurement.

reagent cap open/close mechanism A mechanism that prevents evaporation by automatically opening and closing the **cobas e** pack caps before and after reagent pipetting or operation.

reagent compartment A temperature-controlled section on an analyzer that holds reagents and diluents.

reagent disk The device in the reagent compartment into which the **cobas c** packs or **cobas e** packs are placed.

reagent mask A function that automatically stops analysis of the current test when a required reagent (cobas c pack or cobas e pack) is empty or not present on the system. A red bar appears on the test key in the test selection screen.

reagent pack A complete set of physically combined and ready-to-use reagent bottles for Elecsys assays. The components of a reagent pack cannot be interchanged with another reagent pack. See also *cassette*, *cobas c pack*, and *cobas e pack*.

reagent pack calibration (R-cal) The calibration performed when a reagent has been on board the analyzer more than 24 hours. A reagent pack calibration is valid for one specific reagent pack only.

reagent pack number A unique number on the reagent bottle label that identifies each reagent pack.

reagent probe Probe used to transfer reagents from the reagent bottles to the reaction cells.

reagent probe rinse station An area located between the reagent disks and reaction disk where reagent probes are rinsed both internally and externally with water.

reagent scan A scan of the reagent disk to read information from the reagent barcode into the analyzer and to update the inventory.

real time The display of information on the monitor at the very moment a change to such information occurs.

realtime QC Real-time quality control. A method in which two quality control samples of low and high values are measured, the quantitative values are judged in real time, and an alarm is generated if necessary.

recalibration The repetition of a calibration.

reference electrode 1. Electrode through which the reference solution flows to provide a reference potential for ISE measurements (also called reference cartridge). 2. A part of the measuring cell used to control the electrochemical process of the ECL reaction.

reference range See *expected range*.

reference solution A KCl solution aspirated through the ISE reference cartridge. Also know as the REF, ISE Ref. or reference electrode solution. See reference electrode (1.).

reflex testing A request for additional testing based on customer-defined algorithms or rules and previous test results.

repeat limit A user-definable limit at which a test is run again under unchanged conditions.

reportable range The range of results that can be reported for the assay. It stretches from the lower detection limit to the high end of the calibration curve.

request See order.

rerun The performance of the same test on a sample again under the same or changed conditions.

rerun – concentrated The performance of the same test with a less diluted sample, either by decreasing the diluent or by increasing the sample volume.

Reset Operational mode during which the analyzer sets and aligns all mechanical parts to their home positions.

Result Date/Time The instrument fills the result date and time after the result calculation is finished. It may be maintained by work area management systems for information purpose.

rinse bath See rinse station.

rinse nozzle A nozzle that supplies or drains detergent or water used for rinsing reaction cells.

rinse station A technical device that cleans probes or disposable tips with deionized water or cleaning solutions to avoid contamination and carryover.

Rodbard function A mathematical function used to convert measured signals into concentrations. It uses four parameters to define the shape and position of calibration curves.

S

S.Stop Abbreviation for sampling stop. A system operating mode in which no new samples are pipetted, but samples already pipetted will be completed without interruption or loss.

S1Abs The absorbance of standard solution 1. The displayed value is 10 000 times greater than the actual measured absorbance.

sample blank The absorbance of the sample plus reagent 1 of a photometric test. The sample blank is subtracted from the actual absorbance reading to obtain the absorbance value relevant for the result calculation.

sample cup A small container that is used for samples and also for calibrator and control material. A sample cup can be placed either on specific racks, other inserts, or on sample tubes. Compared to a sample tube, a sample cup allows the use of smaller liquid volumes and so reduces the dead volume.

sample ID A set of alphanumeric data that unmistakably identifies a particular sample. See also *patient ID*.

sample probe Pipetter probe used to transfer sample material from sample containers to reaction cells.

sample rack See rack.

sample tray See rack tray.

sample tube A glass or plastic container for liquid samples to be used with the system. It may or may not have a barcode label, which may be used for positive sample identification. A sample tube contains sample of one specific specimen (sample) type.

sample type One of four types of sample that can be analyzed: serum/plasma, urine, cerebrospinal fluid (CSF), or supernatant. The sample volume and normal value are settable for each type.

sampling stop An instrument alarm level that indicates a problem with the sampling system. See also *S.Stop*.

sandwich principle One of three test principles that can be applied to ECL immunoassays. It is used to detect higher molecular weight analytes, such as TSH. See also *bridging principle*, *competitive principle*.

secondary tube A sample container of variable size into which aliquots are transferred

sequence number A number automatically assigned to each sample by the analyzer and used to track samples and orders.

serum index A function by which the absorbance characteristics of the samples are described to assess the presence of lipemic, hemolysis, and icterus.

serum work area (SWA) The section of a clinical laboratory where all CC, HIA, and HetIA tests (including preanalytical and postanalytical work) are processed.

Service System status that is required to perform a maintenance action. See maintenance item, maintenance procedure.

shutter A door, located on the lid of the reagent disk, that is used to load and unload cobas c packs (reagent cassettes).

sipper A device to aspirate liquid from a vessel into a flow path, for example, ISE measuring flow path. In ECL systems, a device that aspirates the reaction mixture out of the AssayCup as well as ProCell and CleanCell from their reservoirs into the measuring cell.

Sleep mode Also called sleeping. A mechanical and electrical status of an analytical instrument during which no immediate processing can be initiated by the operator.

SMS Selective Mode Solution. SMS is an acidic wash solution which is applied for special washes of reagent probes and reaction cells on the **c** 501 module.

slider A device for raising and lowering the aspiration nozzles from the ProCell and CleanCell bottles.

solid waste container A metal waste container holding a liner that collects discarded solid waste.

standard Traceable reference material used to create a (master) calibration curve. Also referred to as calibrator.

standard deviation A statistic used as a measure of the dispersion or variation in a distribution of data.

standard rack A standardized transportation device for a maximum of five sample containers on Roche Diagnostics/Hitachi High-Technologies instruments.

Stand by An operational mode of the analyzer during which power is on but no sample analysis or maintenance procedures are being performed.

stand by reagent QC The measurement of a quality control sample from a reagent that is on board the analyzer but not presently in use for routine testing.

Start up An operational mode of an analyzer, following power-on, during which the instrument prepares itself for operation.

STAT application A special test application (for example, reduced incubation time) for STAT or emergency samples to achieve faster result reporting.

STAT port Special entry area for STAT samples, which will be processed with priority.

STAT sample Emergency sample. Results should be available within shortest possible time.

SysClean An auxiliary reagent used for the periodic cleaning of the measuring cell.

system cleaning solution See wash solution.

system error 1. A calibration quality criterion that originates from a hardware failure while a calibration measurement is performed.
2. The general term for a case of instrument-related problems.

systematic error An error that is generated by a cause giving deviation to measured values. An alarm generated when control of a low value or a high value is changed in the same direction in realtime quality control.

SysWash A system-specific agent used to avoid reagent carryover. It also prevents bacterial growth.

T

T-mask See Test mask.

target range The allowed range of recovery for an analyte in a control material.

target value The mean of all participant responses after removal of outlying values.

technical limit The dynamic range of an assay.

test code The abbreviated name for a test. This code is displayed on test buttons shown on software screens or windows.

Test mask There are two possibilities to mask a test: Test mask (T-mask) and Patient mask (P-mask). If T-mask is selected, no patient samples, no controls, and no calibrations can be performed. If P-mask is selected, the test is masked for patient samples only—calibration and QC can be performed.

test principle A technique that serves as the basis for designing an assay to detect or quantify analytes.

test protocol The sequence of test steps used to perform an assay (for example, volumes and timings).

ticket master A part of the instrument software that controls the flow of racks on the analyzer.

timeout calibration An instrument mode that automatically generates a calibration request after a predefined interval.

timeout QC A function that measures the quality control sample for the specified item at certain time intervals.

tip See AssayTip.

tip eject station An opening in the instrument housing through which AssayCups and AssayTips are discarded.

tray indication light A light, at the front of the rack loader and unloader that indicates the mode of operation.

tripropylamine (TPA) One of two electrochemically active substances used in the ECL reaction.

turn-around-time 1. The time between the decision to perform a test and the time when the doctor receives the result and can act on it.
2. Inside the laboratory (Lab-TAT): Time between receiving a sample and sending out the validated result.

U

ultrasonic mixer A mechanical unit, in a waterproof pack, that generates ultrasound used to stir samples.

unloader An unloader holds sample racks after the completion of the analytical process.

upload The process of sending data to Roche by a network link.

V

validation The process of checking results or data against defined rules or ranges in clinical laboratories. Validation can be against technical or clinical criteria.

W

wash solution 1. A solution used to wash reaction cells. The unused solution is stored in a detergent bottle in the instrument.
2. A solution used to wash the reagent probes as specified in the **Utility** > **Special Wash** screen.

waste solution reservoir Container that collects reaction waste.

water level sensor A sensor that monitors the water level of temperature-controlled water.

water supply tank A tank used to store ion-exchanged water.

water supply tube A tube for connecting a water supply tank and an analyzer.

workarea consolidation The combination of separate workstations to produce one physical or logical workarea in a laboratory. This combination can be achieved through mechanics (a conveyor, for example), facilitated sample transfer (racks or trays), and data management.

workarea consolidation - workarea consolidation

Index G

Index

Symbols

< >Test (data alarm)
– ISE unit, D–19
<Sig (data alarm)
– e 601 module, D–50
<SigL (data alarm)
– e 601 module, D–40
>AB (data alarm), D–32
>Curr (data alarm)
– e 601 module, D–35
>Cuvet (data alarm)
– photometric unit, D–24
>I.H (data alarm)
– photometric unit, D–15, D–26
>Index (data alarm)
– photometric unit, D–15, D–25
>Kin (data error)
– photometric unit, D–26
>Lin (data alarm)
– photometric unit, D–27
>Proz (data alarm)
– photometric unit, D–28
>React (data alarm)
– photometric unit, D–29
>Rept / <Rept (data alarm)
– photometric unit, D–29
>Rept/ <Rept (data alarm)
– e 601 module, D–38
>Rept/<Rept (data alarm)
– ISE unit, D–18
>Sig (data alarm)
– e 601 module, D–50
>Test /<Test (data alarm)
– photometric unit, D–31
>Test/ <Test (data alarm)
– ISE unit, D–19
>Test/<Test (data alarm)
– e 601 module, D–41

Numerics

3rd Results Acceptance, B–280

A

AB level (e 601 module)
– check error, D–32
– range over, D–32
AB.E (data alarm)
– e 601 module, D–32
Abnormal conditions, during operation, A–20
Abs (data alarm)
– photometric unit, D–21
Access level, E–403
Accumulate Data window, QC menu, E–330
Accumulation
– QC results, B–199, B–215
Accumulation method, E–387
Activate
– controls, B–227
– tests, B–227
ADC.E (data alarm)
– e 601 module, D–33
– ISE unit, D–12
– photometric unit, D–22
Add Control window, QC > Install screen, E–347
Add Operator ID window, E–403
Air Purge window, E–429
Alarm
– alarm indication, D–7
– alarm levels, D–7
– audible, E–67
– calibrations, D–43
– checking, B–34
– code, E–65
– data alarm list, D–10
– data alarms, D–3
– problems without alarm, D–60
– remedy, E–66
– screen, B–34
Alarm list, E–65
Alarm screen
– description, E–65
– Alarm list, E–65
– Sound Setting window, E–67
Alarm Setting window, E–374
Alarm trace
– print screen, E–149
– report, cumulative, E–152
– report, daily, E–151
Analysis
– flow of ISE analysis, A–92
– flow of photometric analysis, A–82
Analyze tab
– e 601 applications, E–492
– Factor area (serum indexes), E–491
– photometric tests, E–486
– Prozone Limit area, E–488
– Qualitative area (serum indexes), E–491
– Reagent Volume area (c 501 (P)), E–489
– serum indexes, E–490

Analyzer
– modules overview, A–36
– safety labels, A–22
– sample tracking, B–98
– shutdown, B–74
– shutdown, sleep mode, B–75
– start, B–30, B–31
– start, automatic, B–32
– start, manual, B–33
Application, B–251
– auto masking, B–265
– automatic rerun, B–271
– installing, B–252
– overview, B–251
– reagents for e 601 module, B–114
– reagents for ISE unit, B–105
– reagents for photometric unit, B–108
– report name, B–271
– technical limit, B–272
– troubleshooting, D–67
– updating, B–258
Application code, E–503, E–507
Application data, A–50
– installation process, A–50
Application parameters
– description, B–260
– description, Analyze tab, B–261
– description, Calib. tab, B–263
– description, Range tab, B–267
– print screen, E–161
– report, E–162
Application screen, E–484
Application settings
– auto masking, e 601 module, B–265
– automatic rerun, e 601 module, B–271
– calibration timeouts, e 601 module, B–266
– dilution rations, e 601 module, B–262
– duplicate limit, e 601 module, B–264
– expected values, B–274
– qualitative fields, c 501 module, B–273
– repeat limit, B–272
– report name, e 601 module, B–271
– technical limit, c 501 module, B–272
– unit of measure, change after calibration, e 601 module, B–269
Approved parts, A–8
Archive
– saving patient data, B–91
– saving system parameters, B–310
Aspiration tube
– clean, e 601 module, C–143
Assay tip buffer station, e 601 module, A–104
AssayCup Discarding window, e 601, E–461
AssayCup, replace, B–139
AssayTip, replace, B–139
Assigning
– calibrator positions, B–178
– QC racks and positions, B–219
– rerun rack manually, B–87
– tests or profiles to test keys, B–281
– tests to e 601 module, B–288, B–289
– tests to module, B–288
Assignment window, E–302
Auto calibration
– c 501 (ISE), E–495
Auto calibration timeout
– c 501 (ISE), E–495
– photometric tests, E–498
Auto masking
– c 501 (ISE), E–494
– check box, E–392
– Utility,Application screen, B–265
Automatic power ON, B–32
Automatic Printout window, E–418
Automatic QC, B–198
– configuration, B–228
– configuring measurement, B–228
Automatic rerun, B–67, B–271, E–504, E–508
– area on Start Condition screen, E–188
Auxiliary reagents
– c 501 module, ISE applications, B–105
– c 501 module, photometric applications, B–108
– e 601 module, A–106, B–114

B

Background maintenance, C–34, C–36, C–37
Backup
– function, A–49, A–51
– patient data, B–91
– reports, Backup Disk Write window, E–74
– system parameters, B–310
Backup Data File, E–467
Backup Data window
– button, E–231
– Data Review screen, E–230
– File Format area, E–231
Backup Disk Write window, E–74
Backup operation, B–240, E–9, E–26
– activating backup operation mode, B–240
– measuring samples in backup operation mode, B–242
backup wait for rack setting
– status, B–233
Barcode
– barcode mode, B–201
– non-barcode mode, B–201
– rack barcodes, A–114
– read error, B–86
– sample barcodes, A–114
– types, A–114

Barcode Read Error window
– buttons, E–213
– Sample area, E–213
– sample list, E–213
– Test Selection screen, E–213
Barcode reader
– c 501 module, for c pack, A–75
– check report, E–184
– e 601 module, A–98
– rack sampler, A–55
– safety information, A–30
Barcode Reader Check window, E–470
Barcode Setting window, E–373
Basics, software, B–3
Bath detergent, A–79
Bead Mixer Check window, e 601 module, E–478
Bead Mixer Wash window, e 601 module, E–446
Beadmixer
– See, microbead mixer.
Biased result, D–81
– enzyme results, D–84
– photometric unit, troubleshooting, D–81
Biohazardous materials, A–9
Bubbles in syringes, D–73
Buttons, B–8
– calibration and QC select, B–51
– daily maintenance, B–43
– global, B–10
– maintenance, B–284
– parameter download, B–58
– pipe setting, B–284
– power up pipe, B–284
– rack delivery, B–284
– reagent overview, B–124, B–141
– reagent preparing, B–44
– sample data clear, B–44
– sample tracking, B–60
– standard, B–9

C

c 501 (ISE)
– auto calibration timeout, E–495
– automatic rerun, E–504, E–508
– define control interval time, E–504, E–508
– define repeat limit, E–504, E–508
– define technical limit, E–504
– expected values, E–506, E–509
– qualitative evaluation, E–505
c 501 (P)
– automatic rerun, E–504, E–508
– qualitative evaluation, E–505
c 501 module, A–65
– assign test, B–288
– auxiliary reagents, ISE applications, B–105
– auxiliary reagents, photometric applications, B–108
– barcode reader, c pack, A–75
– c pack, loading and unloading, B–127
– c pack, unloading and reloading, B–109
– c pack, volume control, B–109, B–116
– calibration concept, B–158
– components, A–68
– extended power OFF, C–111
– front door, A–86
– inactivating, B–290
– ISE unit, A–40, A–89, B–45
– maintenance schedule, C–65
– module overview, A–39, A–67
– operator-related reagent management, B–124
– photometric unit, A–39, A–79, B–49
– photometric unit, wavelengths, A–120
– reaction bath, A–78
– reaction cell rinse units, A–80
– reaction disk, A–77
– reaction monitoring, A–85
– reaction system, specifications, A–119
– reagent concept, B–105
– reagent dispensing system, A–73
– reagent management system, A–75
– reagent overview, B–141
– reagent probe, A–73
– reagent probes, location, A–73
– reagent storage compartment, A–72
– reagent syringes, A–74
– reagent system, A–72
– reagent system, specifications, A–120
– reagent, replace, B–131
– reagents, B–111
– rear view, A–88
– rinse station, ISE unit, A–91
– rinse station, reagent probe, A–74
– rinse station, sample probe, A–71
– sample probe, A–70
– sample syringe, A–71
– sampling system, A–70
– sampling system, specifications, A–119
– special wash, programming, B–297
– specifications, A–119
– stirrer units, A–78
– system characteristics, A–67
– troubleshooting, D–74, D–78
– vacuum system, A–87
c 501 module maintenance
– as needed, C–106
– daily, C–68
– every six months, C–101
– every three months, C–98
– monthly, C–84
– periodic replacement, C–67
– weekly, C–77

c pack
– calibration, B–161
– disposal, A–76
– load, B–49, B–127
– loading port, A–75
– registration, B–109, B–116
– reload, B–109
– unload, B–109, B–127
– volume control, B–109, B–116
c 501 (ISE unit)
– data alarm, D–12
c 501 (photometric unit)
– data alarm, D–20
Cal.E (Calib flag)
– ISE unit, D–44
Cal.E (Sample flag)
– e 601 module, D–33
– ISE unit, data alarms, D–13
– photometric unit, D–23
Calc. Test screen, E–520
Calc.? (data alarm)
– e 601 module, D–33
– ISE unit, D–13
– photometric unit, D–22
Calculated test
– data alarm (photometric unit), D–22
– data alarm, ISE unit, D–13
– deleting formula, B–294
– editing formula, B–292
– programming, B–291
Calculated Test Formula window
– defining formulas, E–523
– Formula tab, E–524
– Range tab, E–525
Calculated tests
– Calc.Test screen, E–521
– expected values, E–526
Calculation
– not possible, e 601 module, D–33
– not possible, ISE unit, D–13
Calib. tab
– e 601 module tests, E–500
– ISE tests, E–494
– photometric tests, E–496
Calibration
– alarm list, D–43
– auto calibration, B–265
– automatic, B–156
– c 501 (ISE) automatic calibration, E–495
– c pack, B–161
– calibrators for e 601 module, B–122
– calibrators for photometric unit, B–110
– cancelling calibrations manually, B–167
– cannot be performed, e 601 module, D–87
– changeover, c 501 (P) applications, E–499
– checking calibrations of e 601 tests, B–174
– checking calibrations of ISE tests, B–173
– checking calibrations of photometric tests, B–169
– checking results, B–57
– concept, B–155, B–197
– concept, c 501 module, B–158
– concept, e 601 module, B–162
– concept, ISE unit, B–159
– e 601 automatic calibration, E–501
– e pack, B–163
– edit concentration values, B–189
– factors, B–176
– ISE unit, B–193
– loading calibrator data, B–184
– loading calibrators, B–55
– loading vials, B–180
– lot, c 501 module, B–161
– lot, e 601 module, B–163
– masking, B–165
– measuring calibrators, B–56
– not released, e 601 module, D–87
– overview over calibration menu, B–166, B–202
– printing load list, B–52
– QC after calibration, B–199
– quality criteria, e 601 module, B–164
– recommended, E–14
– remaining time, E–268
– request, B–53
– requesting calibrations manually, B–167
– review data, B–169
– review measurement details of the most recent calibration, B–171
– review results of previous calibrations, B–172, B–175
– review results of previous ISE calibrations, B–174
– rules, c 501 module, B–158
– rules, e 601 module, B–162
– select button, B–51
– selecting tests for start-up calibration, B–177
– software screen, B–24
– test points, D–83
– tests during operation, B–194
– timeouts, B–266
– troubleshooting, e 601 module, D–87
– validating, B–57
Calibration and QC Load List
– load calibrators and controls, B–55
– printing, B–53
Calibration and QC Select
– System Overview screen, E–7
– window, E–13
Calibration and QC Select window
– Calibration area, E–14
– Load List area, E–15
– QC area, E–14
Calibration and QC Select, operation, B–51
Calibration calibrator screen, B–178

Calibration error
– e 601 module, D–33
– ISE unit, D–44
Calibration failure data
– ISE unit, D–13
– photometric unit, D–23
Calibration install screen, B–181
Calibration load list
– report, E–101, E–110
Calibration Mask Setting window, E–392
Calibration menu
– calibration calibrator screen, B–178
– calibration install screen, B–181
– calibration status screen, B–166
– Calibrator screen, E–296
– Install screen, E–300
– Status screen, E–267
Calibration monitor
– check box, E–418
– report, E–121
Calibration quality criteria, e 601 module, E–283
Calibration request list
– print screen, E–119
– report, E–120
Calibration result list
– report, E–118
Calibration Result window, E–277
Calibration status screen, B–166
Calibration tab
– Print screen, E–99, E–107
– See also, Calibration menu.
Calibration trace
– print screen, E–111
– report, c 501, E–114
– report, c 501 (ISE), E–112
– report, e 601 module, E–115
Calibration Trace window, E–271
Calibrator
– assign positions, B–178
– checking information about installed calibrators, B–182
– loading, B–55
– loading data, B–184
– loading vials, B–180
– measuring, B–56
– rack assignment, E–298
Calibrator data, A–50
Calibrator list
– Calibrator Rack Assignment window, E–299
– Calibrator screen, E–297
Calibrator load list
– print screen, E–109
Calibrator Rack Assignment window, E–298
Calibrator screen, E–296
Calibrators and controls
– e 601 module, B–122
– photometric unit, B–110
Calling
– Roche service representative, D–68
Cap open/close mechanism, A–98
Cap open/close mode
– e 601 applications, E–493
Cap Opener Check window, e 601 module, E–477
CarOvr (data alarm)
– e 601 module, D–34
Carriage, A–104
Carryover
– CarOvr (data alarm), D–34
– evasion, B–297
Cartridge
– measurement, A–91
– reference, A–91
Cassette
– disposal, A–75
– loading port, A–75
– table, A–75
Cassette*see also* c pack
CD drive, computer components, A–45
Cell blank
– abnormal (data alarm), D–24
– measurements report, E–166
– print screen, E–165
Cell blank measurement
– report, E–166
Cell Blank Measurement window, E–427
Cell cover
– clean the cell covers, C–79
Cell Detergent Prime window, E–433
Cell rinse nozzles
– replace nozzle tips, C–106
Cell wash
– c 501 module, B–300
– programming, c 501 module, B–300
– special wash, Chemistry tab, E–530
– washing reaction cell, c 501 module, B–300
Cell.T (data alarm)
– e 601 module, D–34
Changeover, application calibrations, E–499
Check boxes, B–8
Check Digit window, E–410
Check Disk window
– Backup Data File, E–467
– check sum, E–467
– description, E–466
– Media area, E–467
– Mode area, E–467
– software version, E–467
Check sum, E–467

Checking
– abnormal sound, A–20
– alarms, B–34
– calibration and QC results, B–57
– calibration factors, B–176
– calibrations of e 601 tests, B–174
– calibrations of ISE tests, B–173
– calibrations of photometric tests, B–169
– information about installed calibrators, B–182
– results, B–70
– water leakages, A–20
Chemistry tab
– Calibration > Install, E–300
– Utility > Special Wash, E–529
Chemistry, troubleshooting, D–68
Chloride
– ion-selective electrode, A–91
– low value, D–77
ClcT.E (data alarm)
– ISE unit, D–13
– photometric unit, D–22
CleanCell
– bottles, A–107
– clean aspiration tubes, C–143
– clean nozzles, C–121
– clean stand, C–143
– replace reservoir, C–121
– replace trouble, D–85
– replace when empty, B–132
– replace when not empty, B–135
Cleaning (c 501 module) *see* Maintenance works (c 501 module)
Cleaning (core unit) *see* Maintenance works (cu 150)
Cleaning (e 601 module) see Maintenance works (e 601 module)
Cleaning solution
– c 501 module, A–87
– e 601 module, A–106
Clot detection, A–99
Clot.E (data alarm)
– e 601 module, D–34
CmpT.? (data alarm)
– ISE unit, D–14
– photometric unit, D–23
CmpT.E (data alarm)
– ISE unit, D–14
– photometric unit, D–23
cobas c pack, B–108
cobas e pack, B–114
cobas link
– backup function, A–49, A–51
– e-barcodes, A–49
– e-barcodes,application data, A–50
– e-library, A–48
– e-package inserts, A–49, A–51
– main funktions, A–49
– Overview, A–47
– PC, A–48
– working with **cobas** link functions, A–50
Code 39, check box, E–410
Color scheme
– module overview area, B–39
– Status line, B–37
– test matrix, B–81, E–208
– Test Review window, E–233
– Work Flow Guide area, B–37
Comment Title window, E–383
Comment window, Individual QC Chart, E–325
Commissioning, A–6
Communication trace
– print screen, E–154
– report, E–155
Compensated limit, ISE applications, E–494
Compensated test
– Calc.Test screen, E–521
– formula deleting, B–296
– formula editing, B–296
– programming, B–295
Compensated Test Formula window, E–527
Compensation error
– calculation error, ISE unit, D–14
– calculation error, photometric unit, D–23
– data error, ISE unit, D–14
– data error, photometic unit, D–23
Components
– c 501 module, A–68
– consumables area, e 601 module, A–103
– control unit, A–45
– control unit computer, A–45
– core unit, A–52
– e 601 module, A–96
– ISE unit, c 501 module, A–89
– keyboard, A–46
– measuring area, e 601 module, A–99
– mouse, A–46
– PreClean area, e 601 module, A–101
– printer, A–46
– reaction disk, c 501 module, A–77
– reagent area, e 601 module, A–97
– reagent dispensing system, c 501 module, A–73
– reagent probe rinse station, c 501 module, A–74
– reagent system, c 501 module, A–72
– sample pipetter, c 501 module, A–70
– sample probe rinse station, c 501 module, A–71
– sample syringe, c 501 module, A–71
– sampling system, c 501 module, A–70
– touchsreen monitor, A–46
Computer
– CD drive, A–45
– control unit components, A–45
– hard disk, A–45
– keyboard, A–46

– mouse, A–46
– printer, A–46
– touchscreen monitor, A–46
– troubleshooting, D–67
Concentrated waste tank, C–50
Concept
– calibration concept, B–155, B–197
– calibration concept, c 501 module, B–158
– calibration concept, e 601 module, B–162
– calibration concept, ISE unit, B–159
Cond.E (data alarm)
– ISE unit, D–44
Conditioning error, D–44
Conditions
– environmental, A–113
– for system operation, A–112
Configuration
– immunological tests, B–251
– Module Set, B–287
– photometric tests, B–251
– report format, B–306
– system configuration, B–277
Configuring
– automatic QC measurement, B–228
– realtime QC, B–215
Confirmation window
– new calibrator, e 601 module, E–303
Consumables
– area, e 601 module, A–103
– replace, e 601 module, B–139
Container, sample, A–61, A–116
Control
– checking results, B–57
– loading, B–55
– measuring, B–56
– request, B–53
– troubleshooting, photometric unit, D–82
– validating, B–57
Control data, A–50
– load, B–221
Control interval time
– c 501 (ISE), E–504, E–508
– c 501 (P), E–504, E–508
– e 601 module, E–504, E–508
Control list
– Control screen, E–340
– Install screen, E–345
– QC Rack Assignment window, E–342
Control Lot No. list
– Select Chart window, E–326, E–339
– Select Control window, E–331
Control screen
– buttons, E–341
– Control list, E–340
– QC menu, E–340
– QC Rack Assignment window, E–342
Control unit, A–45
– components, A–45
– computer, A–45
– module overview, A–37
– monitor, A–46
– mouse, A–46
– printer, A–46
Controls
– activate tests, B–227
– data alarm, D–55
– edit values, B–224
– reassign control values, B–225
– recovery, e 601 module, D–91
Cooling fans
– clean the cooling fan, C–60
Core unit, A–52, A–118
– audible alarms, E–67
– barcode reader, A–55
– components, A–52
– cooling fan, C–60
– maintenance schedule, C–49
– module overview, A–38
– power switches, A–56
– rack loader, unloader, A–54
– rack rotor, A–58
– rack sampler, A–53
– specifications, A–118
– STAT port, A–55
– water supply, A–57
Core unit maintenance
– as needed, C–61
– daily, C–50
– every six months, C–58
– monthly, C–53
Cover
– reagent disk, e 601 module, D–85
cu 150 *see* Core unit
Cumulative alarm trace report, E–152
Cumulative operation list
– print screen, E–158
Cumulative operations list
– report, E–159
Cumulative QC, B–197
Cumulative QC chart
– print screen, E–138
– report, E–139
Cumulative QC Chart window
– button, E–338
– chart list, E–337
– Cumulative screen, E–336
Cumulative QC list
– print screen, E–142
– report, E–143

Cumulative screen
– buttons, E–335
– Cumulative list, E–334
– Cumulative QC Chart window, E–336
– QC menu, E–334
Cup, A–59
– sample, A–61
– See, AssayCup.
Curr.E (data alarm)
– e 601 module, D–35
Customizing
– patient report, B–306
Cuvette history
– print screen, E–171
– report, E–172

D

Daily alarm trace report, E–151
Daily Maintenance button
– System Overview screen, E–7
Daily maintenance button, B–43
Daily operation *see* Operation
Data
– accumulation of QC results, B–199
– archive patient data, B–91
– calibration, B–169
– load control data, B–221
– loading calibrator data, B–184
– patient, archiving, B–91
– result, drifting, D–60
– result, high level, D–61
– result, low level, D–61
Data alarms, D–3
– 501 (ISE unit), D–12
– 501 (photometric unit), D–20
– all listed, D–10
– e 601 module, D–32
– for controls, D–55
– introduction, D–7
Data loss, A–18
Data monitor
– comparison of data monitor format and report format, B–309
– customazing patient reports, B–306
– report, monitor format, B–309
– report, report format, B–309
Data monitor report
– monitor format, E–79
– print screen, E–77
– report format, E–81
Data Print screen, E–77
Data Print, operation, B–72
Data problems, D–60
Data problems without alarms, D–60
Data Review screen, E–216
– Backup Data window, E–230
– buttons, E–220, E–247
– Data list box, E–217
– Delete Record confirmation window, E–230
– fields, E–217
– Filter area, E–217
– Filter window, E–225
– Read Backup Disk window, E–222
– sample selection list, B–89, B–96, E–218, E–246
– Search Sample window, E–223
– Send To Host window, E–227
– test results list, B–90, B–97, E–219, E–247
– Test Review window, E–232, E–235
Data review screen, B–88, B–96
Data security, A–18
Date Range
– Alarm Trace print screen, E–150
– Cumulative QC Chart print screen, E–138
Decommissioning, A–6
Decreased sample concentration, D–63
Default Profile Per Sample Type window, E–198
Default setting
– See, Start up setting.
Default values
– application parameters, E–506, E–509
Deleting
– calculated test formula, B–294
– compensated test formula, B–296
– rerun rack manually, B–87
Demographics window, E–211
– Patient Information area, E–212
– sample information, E–211
– Test Selection screen, E–211
Description
– application parameters, B–260
– application parameters, Analyze tab, B–261
– application parameters, Calib. tab, B–263
– application parameters, Range tab, B–267
Description & Remedy, E–66
Det.S (data alarm)
– photometric unit, D–25
Detail window
– Reagent Overview window, E–37
– test results, E–238
Deviation
– method comparison, D–93
– module to module variance, e 601 module, D–92
Device, electromagnetic, A–8
Diff.E (data alarm)
– e 601 module, D–45
Diluents
– c 501 module, B–110
– e 601 module, B–120

Diluted sample
– automatic dilutions, B–69
– dilution from Host, B–69
– manual dilutions, B–69
– rerun, B–68
Dilution
– automatic, B–69
– from Host, B–69
– manual, B–69
– prediluted sample, B–69
– ratios, e 601 module, B–262
Dimensions, module, A–111
Direct Help, B–20
Dispenser
– PreClean area, e 601 module, A–101
Disposal
– c pack, A–76
– Instrument, A–32
– of the analyzer, A–6
– openings, e 601 module, A–104
Download
– application data, A–50
– calibration data, A–50
– control data, A–50
– e-barcodes, A–49
– parameter, B–58
– test selection, B–62
Downloading
– application parameter, B–255
Drift, troubleshooting, e 601 module, D–86
Dup.E (data alarm)
– e 601 module, D–46
– photometric unit, D–45
Duplicate error
– e 601 module, D–46
– photometric unit, D–45
Duplicate limit
– defining, e 601 module, B–264
– Dup.E data alarm, c 501 module, D–45
– Dup.E data alarm, e 601 module, D–46
– e 601 module, E–500
DVD
– Finalizing a DVD disk, B–246
– Formatting a DVD disk, B–245
– Preparing a DVD disk, B–244

E

e 601
– automatic calibration, E–501
– automatic rerun, E–504, E–508
– control interval time, E–504, E–508
– expected values, E–506, E–509
e 601 module, A–93
– assign test, B–288
– auxiliary reagents, A–106, B–114
– calibration concept, B–162
– calibrators and controls, B–122
– checking calibrations of e 601 tests, B–174
– components, A–96
– consumables area, A–103
– consumables, replace, B–139
– data alarms, D–32
– diluents, B–120
– dilution ratios, B–262
– drift troubleshooting, D–86
– duplicate limit, B–264
– e pack, B–115, B–118, B–120
– ECL unit, specifications, A–123
– erratic results, D–86
– extended power OFF, C–152
– finalization, C–151
– green indicator lamp, A–105
– gripper, A–104
– inactivating, B–290
– incubator disk, A–100
– inventory update, B–151
– magazine lifter, A–104
– magazine waste compartment, A–105, C–149
– maintenance schedule, C–117
– measuring area, A–99
– measuring cell, A–100
– method comparison, D–93
– microbead mixer, A–98
– module overview, A–40, A–95
– module to module variance, D–92
– PreClean area components, A–101
– PreClean bottles, A–106, A–107
– ProbeWash station, A–98
– reaction system, specifications, A–122
– reagent area, A–97
– reagent concept, B–114
– reagent disk, A–98
– reagent overview, B–147
– reagent probe, A–98
– reagent reloading, B–128
– reagent syringe, A–98
– reagent system, specifications, A–123
– reagent, replace, B–132
– reagents, B–122
– replace reagents, B–50
– rinse station, microbead mixer, A–97
– rinse station, PreClean area, A–101
– rinse station, reagent probe, A–97
– rinse station, sample probe, A–99
– rinse station, sipper probe, A–99
– sample probe, A–99
– sample syringe, A–100
– sampling system, specifications, A–122
– sipper probes, A–100
– sipper syringes, A–100
– solid waste, B–139

– solid waste container, A–105
– solid waste, empty, B–140
– special wash, programming, B–304
– specifications, A–122
– system characteristics, A–95
– troubleshooting, D–85
– troubleshooting calibration, D–87
– vortex mixing station, A–104
e 601 module maintenance
– as needed, C–143
– daily, C–118
– every two weeks, C–137
– three months, C–140
– weekly, C–121
e pack, B–115, B–118, B–120
– calibration, B–163
– reload reagent, B–128
e-barcodes, A–49
– application data, A–50
– calibrator data, A–50
– control data, A–50
ECL unit
– specifications, A–123
EcoTergent, A–79
Edit Calibrator window, E–307
Edit Cell Wash window
– c 501 (P), E–533
– c 501 (P), R1 area, E–533
– c 501 (P), R2 area, E–534
Edit Control window
– Individual area, E–352
– Install screen, E–351
– Test list, E–352
Edit Maintenance Type window, E–394
Edit Pipe window, E–398
Edit Reagent Probe Wash window
– c 501 (P), E–532
– Detergent area, E–532
– From Reagent area, E–532
– Probe area, E–532
– To Reagent area, E–532
Edited (data alarm)
– e 601 module, D–35
– ISE unit, D–14
– photometric unit, D–25
Editing
– calculated test formula, B–292
– compensated test formula, B–296
– concentration values, B–189
– control values, B–224
– maintenance pipes, C–11
– maintenance types, C–19
Elecsys area
– Reagent Parameter Setting window, E–432
Electrical safety, A–11
Electrical supply
– power not available, D–71
Electromagnetic devices, A–8
e-library, A–48
– e-barcodes, A–49
– e-package inserts, A–49, A–51
Empty PC/CC Reservoir window, e 601 module, E–458
Empty solid waste
– e 601 module, B–140
Environmental conditions, A–7, A–113
e-package inserts, A–49, A–51
Erratic result
– e 601 module, D–86
– ISE unit, D–74
– photometric unit, troubleshooting, D–79, D–81
Erroneous operation, D–60
Error
– barcode read error, B–86
– calibration, e 601 module, D–33
– calibration, ISE unit, D–44
– QC error 1, D–56
– QC error 2, D–57
– random error, realtime QC, D–57
Expected values
– c 501 (ISE), E–506, E–509
– c 501 (P), E–506, E–509
– calculated test, E–526
– changing, B–274
– e 601 module, E–506, E–509
Expired reagents, E–375
Extended power OFF, C–111, C–152

F

F1 Help, E–57
– See, Online Help
False bottom tube, E–370
Favorite tab
– Online Help, B–19
Filter window
– Data Review screen, E–225
– Results Send To Host area, E–225
– Sample area, E–225
– Sample Status area, E–225
– Type area, E–225
Filters
– circuit board rack filter, c 501 module, C–96
– detergent aspiration filter, c 501 module, C–94
– KCl aspiration filter, c 501 module, C–84
– power supply filter, c 501 module, C–96
– rack sampler unit, C–57
– radiator filter, c 501 module, C–96
– water filter, C–58
Finalization
– Finalization window, E–457
Finalization, e 601 module, C–151

Finalizing a DVD disk, B–246
Firewall, A–18
Floppy disk
– check report, E–182
– format, E–438
Floppy Disk Utility window, E–438
Flow path
– cleaning, c 501 module, C–69
– cleaning, e 601 module, C–137
Formatting a DVD disk, B–245
Front doors
– c 501 module, A–86
Functions
– backup, A–49, A–51
– working with **cobas** link, A–50

G

General maintenance, C–3
Global buttons, B–10, E–56
Global screens
– Alarm screen, E–65
– Logoff screen, E–59
– Logon screen, E–63
– Print screen, E–68
– S. Stop screen, E–64
– Start Conditions screen, E–186
– Stop screen, E–58
Green indicator lamp, e 601 module, A–105
Green rack
– wash with rack, E–398
Gripper
– e 601 module, A–104
– PreClean area, e 601 module, A–101
Gripper Check window, e 601 module, E–479
Guidance prompt, B–6

H

Hacker attack, A–18
Hard disk
– check report, E–179
– control unit components, A–45
– saving space on, B–44
Help
– See, Online Help.
High level
– result data, D–61
High result, photometric unit, D–78
High value
– ISE internal standard, D–76
– sodium, D–77
Host Communication Setting window
– Communication Setting tab, E–376
– description, E–376
– RS232C Setting area, E–377
– Text Setting tab, E–378
Host communication, Start Conditions screen, E–188
Host interface, A–113
Host Test Code Setting window, E–382

I

Immune tab (Calibration > Install), E–300
Immune tab (Utility > Special Wash)
– Special Wash screen, E–536
Immunoassay, troubleshooting, D–69
Immunological tests
– configuration, B–251
Inactivating
– module, B–290
Inc.T (data alarm)
– e 601 module, D–36
Increased sample concentration, D–63
Incubation Water Exchange window, E–428
Incubator
– Bath detergent, A–79
– clean, e 601 module, C–128
– e 601 module, A–100
– temperature, data alarm, D–36
Incubator bath
– clean the incubator bath, c 501 module, C–88
Indicator lamp
– green, e 601 module, A–105
Individual and cumulative QC, B–197
Individual QC chart
– print screen, E–129
– report, E–131
Individual QC Chart window
– buttons, E–324
– chart list, E–323
– Comment window, E–325
– QC menu, E–322
– Select Chart window, E–326
Individual QC list
– print screen, E–135
– report, E–136
Individual screen
– buttons, E–321
– individual list, E–320
– QC menu, E–320
Initial Bead Mixing window, E–459
Initialize
– status, B–233
Insoluble contaminants in sample, A–14
Inspection
– before start, B–30
Install screen (Calibration)
– buttons, E–301
– Calibration menu, E–300
– Calibrator list, E–301
– Chemistry/Immune tabs, E–300

– Test list, E–301
Install screen (QC)
– Add Control window, E–347
– buttons, E–346
– Control list, E–345
– Edit Control window, E–351
– QC menu, E–344
– Test list, E–345
Installation, A–6
– of the analyzer, A–6
Instrument
– alarms, E–65
– care, C–23
– clean surfaces, cu 150 module, C–61
– clean surfaces, e 601 module, C–110, C–150
– covers, A–10
– troubleshooting, D–69, D–70
Instrument care
– automating with maintenance pipes, C–32
Instrument Factor window, E–292
Instrument status, B–233
– during maintenance, C–6
Insufficient PreClean, D–42
Insufficient reagent alarm
– e 601 module, D–37
– ISE unit, D–17
Inter assay precision
– e 601 module channels, D–92
Interface
– Host, A–113
– user interface, general description, B–5
Internal standard
– high/low values, D–76
Intra assay precision
– e 601 module, D–91
Introduction
– data alarms, D–7
Inventory list, Reagent > Status screen, E–262
Inventory Set window, E–264
Inventory Update window, E–453
Inventory update, e 601 module, B–151
IS bath, A–90
– clean IS bath, C–83
– remove IS bath, C–83
ISE Check window, E–468
ISE Ref.
– clean aspiration filter, C–84
ISE unit
– calibration, B–193
– calibration alarm, Cal.E, D–44
– calibration alarm, Cond.E, D–44
– calibration alarm, IStd.E, D–46
– calibration alarm, Prep.E, D–47
– calibration alarm, Rsp1.E, D–48
– calibration alarm, Rsp2.E, D–48
– calibration alarm, Slop.E, D–51
– calibration concept, B–159
– checking calibrations of ISE tests, B–173
– components, A–89
– data alarm, < >Test, D–19
– data alarm, >Rept/<Rept, D–18
– data alarm, >Test/<Test, D–19
– data alarm, ADC.E, D–12
– data alarm, Cal.E, D–13
– data alarm, Calc.?, D–13
– data alarm, ClcT.E, D–13
– data alarm, CmpT.?, D–14
– data alarm, CmpT.E, D–14
– data alarm, Edited, D–14
– data alarm, ISE.E, D–16
– data alarm, ISE.N, D–16
– data alarm, Mix.E, D–17
– data alarm, Mix.L, D–17
– data alarm, Over.E, D–17
– data alarm, Reag.S, D–17
– data alarm, Samp.C, D–18
– data alarm, Samp.S, D–18
– erratic result, D–74
– flow of analysis, A–92
– internal standard value, D–76
– IS bath, A–90
– low values, D–77
– measuring system, A–91
– overview, A–40
– pipetting system, A–90
– reagent compartment, A–91
– reagents for applications, B–105
– replace reagents, B–45
– rinse station, A–91
– sipper mechanism, A–90
– sipper syringe, air in, D–74
– specifications, A–121
– troubleshooting, D–74
ISE.E (data alarm), D–16
ISE.N (data alarm), D–16
Isolation
– mechanical problem, D–71
IStd.E (data alarm)
– ISE unit, D–46
ITF check box, E–410

J

Jump window, E–72

K

K factors
– Working Information window, c 501 (P), E–285
Key
– shortcut keys, B–11
– test key, B–281

Key Setting window, E–384
Keyboard, A–46

L

Labels
– front view, A–24
– rear view, A–29
– safety labels of the system, A–22
– side view, A–26
– top view, A–27
Lamp
– green indicator lamp, e 601 module, A–105
Legend
– Sample Tracking window, E–20
Levey-Jennings chart
– Cumulative QC Chart window, E–338
– Individual QC Chart window, E–323
Lifter
– See, magazine lifter.
Linearity, data alarm, D–27
Liquid Flow Path Cleaning window, E–452
Liquid flow path cleaning, e 601 module, C–137
Liquid level detection
– reagent probe, e 601 module, A–98
– Sample LLD data alarms, e 601 module, D–40
– sample probe, c 501 module, A–70
– sample probe, e 601 module, A–99
List
– calibration alarm, D–43
– data alarm, D–10
– maintenance checks, C–43
– maintenance items, C–38
– rerun, D–63
List boxes, software basics, B–7
Load list
– calibration, E–110
– calibrator and QC load list, B–52
– reagent load list, B–45
Loading
– c pack, B–127
– calibrator vial, B–180
– calibrators, B–55
– control data, B–221
– controls, B–55
– routine samples, B–63, B–66
– samples and reagents, safety information, A–12
– See Downloading
Logoff screen, E–59
Logon screen, E–63
Lot
– calibration, c 501 module, B–161
– calibration, e 601 module, B–163
Low level
– result data, D–61
Low results
– ISE unit, D–77
– photometric unit, D–79
Low signal level (data alarm), D–40
Low values
– chloride, D–77
– ISE internal standard, D–76
– ISE unit, D–77

M

Magazine (e 601 module)
– lifter, A–104
– magazine waste compartment, cleaning, C–149
– replace, B–139
Magazine waste compartment
– e 601 module, A–105
Magazine-related Unit Check window, E–480
Main comment, Comment Title window, E–383
Main menu
– software, B–21
Maintenance
– after routine operation, B–74
– after shutdown, B–76
– background, C–34
– before shutdown, B–74
– button, B–284
– checks, list of, C–43
– concept, C–8
– daily maintenance button, B–43
– definitions, C–8
– general comments, C–6
– general maintenance, C–3
– instrument care, C–23
– instrument status, C–6
– items, list of, C–38
– maintenance types, adding and editing, C–19
– overview, C–5
– parallel, C–34
– perform background maintenance, C–36
– perform parallel maintenance, C–37
– power up pipe, E–400
– remaining time, E–422
– report, C–22, E–169
– reports from Utility > Maintenance, E–179
– schedule, C–23
– select power off pipe, E–398
– status, B–233
– stopping background maintenance, C–37
– stopping parallel maintenance, C–37
– tracking maintenance, C–21
Maintenance (c 501 module)
– as needed maintenance, C–106
– daily maintenance, C–68
– monthly maintenance, C–84
– periodic replacement of parts, C–67

– six months maintenance, C–101
– three months maintenance, C–98
– weekly maintenance, C–77
Maintenance (c 501 module) see Maintenance works (c 501 module)
Maintenance (cu 150)
– as needed maintenance, C–61
– daily maintenance, C–50
– monthly maintenance, C–53
– six months maintenance, C–58
Maintenance (e 601 module)
– as needed maintenance, C–143
– daily maintenance, C–118
– three months maintenance, C–140
– two weeks maintenance, C–137
– weekly maintenance, C–121
Maintenance (e 601 module) see Maintenance works (e 601 module)
Maintenance check
– list of maintenance checks, C–43
Maintenance checks, E–466
Maintenance item
– list of maintenance items, C–38
– performing maintenance item, C–13
– system wash, C–41
Maintenance items, E–423
Maintenance Monitor window, E–422
Maintenance Parameter Setting window, E–393
Maintenance pipe, C–10
– automating instrument care, C–32
– defining and editing maintenance pipes, C–11
– deleting maintenance pipe, C–12
– performing maintenance items or pipes, C–13
– recommended maintenance pipes, C–32
– select power up pipe, C–15
– select sleep pipe, C–17
– select start up pipe, C–16
– using maintenance pipe functions, C–15
Maintenance Pipe Setting window, E–397
Maintenance report
– explanation, E–170
– print screen, E–167
– report example, E–169
Maintenance schedule, C–23
– as needed maintenance, C–30
– c 501 module, C–65
– cu 150, C–49
– daily maintenance, C–24
– e 601 module, C–117
– monthly maintenance, C–28
– six months maintenance, C–29
– three months maintenance, C–29
– two weeks maintenance, C–27
– weekly maintenance, C–26
Maintenance screen
– Maintenance Items list, E–420
– Maintenance Type list, E–420
Maintenance type, C–18
– defining and editing maintenance types, C–19
– indication on System Overview screen, B–43
– tracking maintenance, C–21
Maintenance works (c 501 module)
– cleaning cell covers, C–79
– cleaning cell rinse nozzles, C–75
– cleaning detergent aspiration filters, C–94
– cleaning drain port for high concentrated waste, C–76
– cleaning dust filters (behind front doors), C–96
– cleaning incubator bath, C–88
– cleaning KCl aspiration filter, C–84
– cleaning probes, C–73
– cleaning rinse station, C–81
– cleaning ultrasonic mixers, C–98
– draining the vacuum tank, C–109
– removing and cleaning the IS bath, C–83
– replacing nozzle tips, C–106
– replacing photometer lamp, C–101
– replacing reaction cells, C–86
– rinsing reaction system, C–77
Maintenance works (cu 150 module)
– cleaning instrument surfaces, C–61
Maintenance works (cu 150)
– cleaning concentrated waste tank, C–50
– cleaning cooling fans, C–60
– cleaning filter of rack sampler unit, C–57
– cleaning inlet water filter, C–58
– cleaning water tank, C–53
Maintenance works (e 601 module)
– cleaning incubator, C–128
– cleaning instrument surfaces, C–110, C–150
– cleaning liquid flow path, C–137
– cleaning microbead mixer, C–132
– cleaning mixing station and separation stations, C–125
– cleaning probes and sippers, C–118
– cleaning ProCell/CleanCell aspiration tubes, C–143
– cleaning ProCell/CleanCell nozzles, C–121
– cleaning ProCell/CleanCell stand, C–143
– cleaning reagent disk and compartment, C–146
– cleaning rinse stations, C–134
– cleaning solid waste compartment, C–148
– cleaning vortex mixer, C–130
– replacing pinch valve tubing, C–140
– replacing ProCell/CleanCell reservoirs, C–121
Management
– operator-realated reagent, c 501 module, B–124
Mandatory check box
– test assignment, c 501 (P), E–546
– test assignment, e 601 module, E–547
Manual Cleaning window, E–454
Manual QC, B–199
Manual rerun, B–68
Manual system start-up, B–33
Manual Test window, E–239

Markings, E–209
– test selection matrix, B–82
Masking
– application auto masking, B–265
– calibration, B–165
– module, C–36
Masking window, E–195
Material codes, controls, E–347
MC Exchange window, E–451
MC Preparation window, E–450
Mean-R, B–199
Measurement
– automatic QC, B–228
– cartridges, A–91
– data, accumulation of QC results, B–199
– request QC measurement, B–205
Measuring
– calibrators, B–56
– controls, B–56
Measuring area components, e 601 module, A–99
Measuring cell
– construction, A–100
– temperature alarm, D–34
Measuring cell, e 601 module, A–100
Mechanical problems
– isolation, D–71
Mechanical safety, A–12
Mechanism
– open/close cap, e 601 module, A–98
Mechanisms Check window
– description, E–469
Menu
– main menus, B–21
– menu tabs, software basics, B–7
Method area
– Calibration > Status screen, E–269
– Start Up Setting window, E–295
Method comparison
– e 601 module, D–93
Methods
– accumulation methods for QC results, B–199
– QC, B–197
Microbead mixer
– clean, C–132
– e 601 module, A–98
Minimum sample volume
– c 501 module, A–119
Mix.E (data alarm)
– ISE unit, D–17
– photometric unit, D–27
Mix.L (data alarm)
– ISE unit, D–17
– photometric unit, D–27
Mixing station
– vortex, A–102
Mode
– barcode or non-barcode mode, B–201
Mode,see status
Module
– assigning tests, B–288
– dimensions, A–111
– inactivating, B–290
– masking, C–36
– trouble on each channel in module, D–62
– trouble on each module, D–62
Module list box
– Setting screen, E–251
– Status screen, E–259
Module Masking window, E–197
Module overview area
– color scheme, B–39
– system overview, B–35
Module set
– configuration, B–287
Module Set screen, E–544
Module Setting tab, Rack Assignment window, E–371
Module Setting window, E–549
Module to module variance, e 601 module, D–92
Modules
– c 501 module, A–39
– control unit, A–37
– core unit, A–38
– e 601 module, A–40
– overview, A–33, A–36
– second rotor module, A–41
Monitor, touchscreen, A–46
Monitoring
– reaction, c 501 module, A–85
Mono.E (data alarm)
– e 601 module, D–47
Monotony of curve, D–47
Mouse, A–46
Multi-rule Shewhart method, E–332

N

Non-Standard Tube area, E–370
NW 7 check box, E–410

O

Online Help
– buttons, B–14
– Direct Help, B–20
– F1 Help, B–13, E–57
– favorite tab, B–19
– navigation, B–15
– printing topic, B–20
– searching, B–16
– system, B–13

Operating conditions, A–112
– electrical, A–112
– water requirements, A–112
Operation
– calibrating tests during operation, B–194
– check system alarms, B–34
– erroneous, D–60
– loading routine samples, B–63
– maintenance after shutdown, B–76
– maintenance before shutdown, B–74
– overview, B–29
– preroutine operation, B–43
– preventive action, B–40
– printing data report, B–72
– processing rerun, B–67
– processing samples, B–62
– reagent load list, B–45
– routine operation, B–61
– shutting down the analyzer, B–74
– start processing, B–64
– starting inspection, B–30
– status, B–233
– stop sampling, B–73
– system overview screen, B–35
Operation time, maintenance report, E–170
Operator
– access levels, E–403
– qualification, A–6
– troubleshooting responsibility, D–68
Operator ID
– Logon screen, E–63
– trace print screen, E–156
– trace report, E–157
Operator ID window, E–402
Operator-related reagent management, B–124
Options, option buttons, B–8
Others tab
– c 501 (ISE) tests, E–510
– photometric tests, E–512
Others view, Sample Tracking window, E–21
Over.E (data alarm)
– e 601 module, D–36
– ISE unit, D–17
– photometric unit, D–28
Overlay window, E–243
Overview
– application, B–251
– c 501 module, A–67
– calibration menu, B–166, B–202
– daily operation, B–29
– data review screen, B–88, B–96
– e 601 module, A–95
– modules, A–33, A–35
– reagent overview, c 501 module, B–141
– reagent overview, e 601 module, B–147
– system overview screen, B–21, B–35
– test selection screen, B–80
Overview, system modules, A–36

P

Page X/4, E–364
Parallel maintenance, C–34, C–37
Parameter
– updating application, B–258
Parameter Check
– status, B–233
Parameter Download button, B–58
Parameter Read Write window, E–439
Parameters
– description of application parameters, B–260
– description of application parameters, Analyze tab, B–261
– description of application parameters, Calib. tab, B–263
– description of application parameters, Range tab, B–267
– downloading applications, B–255
– system, B–278
– system, restoring, B–312
– system, saving, B–310
Password, Logon screen, E–63
Patient data, archiving, B–91
Patient Information area
– See, Demographics window.
Photometer, A–79
– flow of analysis, A–82
Photometer Check window, E–426
Photometer lamp, C–101
– Change Light Source Lamps window, E–464
Photometric tests
– configuration, B–251
– multiple reagents, D–83
– qualitative fields, B–273
– technical limit, B–272
– troubleshooting, D–84
Photometric unit, A–79
– calibration alarm, Dup.E, D–45
– calibration alarm, S1A.E, D–48
– calibration alarm, SD.E, D–49
– calibration alarm, Sens.E, D–49
– calibration alarm, Std.E, D–52
– calibration failure, D–23
– calibrators and controls, B–110
– checking calibrations of photometric tests, B–169
– data alarm, >Cuvet, D–24
– data alarm, >I.H, D–15, D–26
– data alarm, >Index, D–15, D–25
– data alarm, >Kin, D–26
– data alarm, >Lin, D–27
– data alarm, >Proz, D–28
– data alarm, >React, D–29

– data alarm, >Rept/<Rept, D–29
– data alarm, >Test/<Test, D–31
– data alarm, Abs, D–21
– data alarm, ADC.E, D–22
– data alarm, Cal.E, D–23
– data alarm, Calc.?, D–22
– data alarm, ClcT.E, D–22
– data alarm, CmpT.?, D–23
– data alarm, CmpT.E, D–23
– data alarm, Det.S, D–25
– data alarm, Edited, D–25
– data alarm, Mix.E, D–27
– data alarm, Mix.L, D–27
– data alarm, Over.E, D–28
– data alarm, ReagEx, D–29
– data alarm, Samp.?, D–30
– data alarm, Samp.C, D–30
– data alarm, Samp.S, D–31
– diluent for photometric tests, B–110
– flow of analysis, A–82
– load **cobas c** pack, B–49
– overview, A–39
– reagents for applications, B–108
– specifications, A–120
– troubleshooting, D–78, D–81
– troubleshooting, biased enzyme results, D–84
– troubleshooting, control, D–82
– troubleshooting, erratic results, D–79, D–81
– troubleshooting, high results, D–78
– troubleshooting, low results, D–79
– troubleshooting, sample, D–82
– troubleshooting, single test, D–82
– wavelengths, A–120
Photomultiplier tube, A–100
Pinch valve
– replace tubing, e 601 module, C–140
Pipe
– status, B–233
Pipe functions, C–15
– power up pipe, C–15
– sleep pipe, C–17
– start up pipe, C–16
Pipe setting, button, B–284
Pipetter
– See, syringe.
Pipetter Air Purge window, e 601 module, E–448
Placing, PreClean, D–86
Plot list
– Select Chart window, E–326, E–339
– Select Control window, E–331
Position list
– Calibrator Rack Assignment window, E–299
– Sample Tracking window, E–17
Post Operation
– status, B–233
Potassium
– ion-selective electrode, A–91
Power
– interruption, A–7
– no electrical power, D–71
– power supply, A–112
– start-up analyzer, B–31
– start-up analyzer, automatic, B–32
– start-up analyzer, manual, B–33
– switches, core unit, A–56
Power interruption, A–7
Power OFF
– extended, c 501 module, C–111
– extended, e 601 module, C–152
– using maintenance pipes, E–398
Power ON, B–31
– after extended power OFF, c 501 module, C–112
– after extended power OFF, e 601 module, C–156
– automatic, B–32
– manual, B–33
Power on time, maintenance report, E–170
Power Up
– status, B–233
– troubleshooting, D–70
Power Up Pipe
– status, B–233
Power up pipe
– buttons, B–284
– selecting, C–15
Power Up Pipe window, E–400
Precision check
– print screen, E–95
– report, E–96
PreClean
– area, e 601 module, A–101
– bottles, e 601 module, A–106, A–107
– dispenser, e 601 module, A–101
– gripper, e 601 module, A–101
– insufficient, D–42
– replace, B–134, B–137
– replace when empty, B–134
– replace when not empty, B–137
– sipper, e 601 module, A–101
– temperature out of range, D–42
– trouble placing, D–86
– vortex mixing station, A–102
Prediluted sample, B–69
Prep.E (data alarm)
– ISE unit, D–47
Preparation
– status, B–233
Preparing a DVD disk, B–244
Preroutine operation, B–43
Pretreatment, B–118

Preventive action
– check box, B–40
– in daily routine, B–40
– System Overview screen, E–6
Pre-wash area
– clean stations, C–125
Pre-wash Gripper Check window, E–483
Pre-wash Probe Check window, E–482
Pre-wash Sipper Air Purge window, E–456
Pre-wash Sipper Rinse window, E–455
Print buffer
– print reports, E–73
– Print View window, E–70
Print screen
– description, E–68
– Calibration tab, E–107
– QC tab, E–129
– Reagent Information tab, E–99
– Utility tab, E–149
– Workplace tab, E–77
Print View window, E–70
– Backup Disk Write window, E–74
– Jump window, E–72
– Print window, E–73
Print window, E–73
Printer, A–46
Printing
– data report, B–72
printing
– Online Help topic, B–20
Probes
– clean probes, c 501 module, C–73
– clean probes, e 601 module, C–118
– does not descend to liquid surface, D–73
– wash reagent probe, c 501 module, B–298
– wash reagent probe, e 601 module, B–304
– wash sample probe, c 501 module, B–302
– wash sample probe, e 601 module, B–305
ProbeWash
– replace when empty, B–135
– station, e 601 module, A–98
Procedure
– troubleshooting, D–67
ProCell
– bottles, A–107
– clean aspiration tubes, C–143
– clean nozzles, C–121
– clean stand, C–143
– replace reservoir, C–121
– replace trouble, D–85
– replace when empty, B–132
– replace when not empty, B–135
ProCell/CleanCell
– clean nozzles, C–121
– replace reservoir, C–121
Processing
– additional samples, B–65
– rerun, B–67
– routine samples, B–62
– start measurement, B–64
– STAT samples, B–65
Profile list
– print screen, E–97
– report, E–98
Profile Setting window, E–386
Programming
– auto QC measurements, B–228
– calculated tests, B–291, B–292
– cell wash, c 501 module, B–300
– compensated test, B–295
– special wash, c 501 module, B–297
– special wash, e 601 module, B–304
– system parameters, B–278
Prozone limit, parameters, E–488
PT link, B–118

Q

Q2.5SD (data alarm), D–57
Q3SD (data alarm), D–56
QC
– accumulation of QC results, B–199, B–215
– after calibration, B–199
– assigning racks and positions, B–219
– automatic measurement, B–228
– automatic measurement, configuring, B–228
– automatic QC, B–198
– checking results, B–57
– configuring realtime QC, B–212, B–215
– controls for e 601 module, B–122
– controls for photometric unit, B–110
– cumulative QC, B–197
– error 1 (1-3S), D–56
– error 2 (1-2.5S), D–57
– individual QC, B–197
– loading controls, B–55
– manual QC, B–199
– Mean-R, B–199
– measurement, system implementations, B–198
– measuring controls, B–56
– methods, B–197
– printing load list, B–52
– realtime QC, B–197, B–198
– request, B–53
– request QC measurement, B–205
– select button, B–51
– software screen, B–25
– standby reagent QC, B–53, B–198, B–206
– timeout, B–198, B–204
– unloading QC racks from the rack rotor, B–229
– validating, B–57

– X-R, B–199
QC calculation, E–387
QC cumulative screen, B–217
QC individual screen, B–209
QC install screen, B–220
QC load list
– print screen, E–144
– report, E–145
QC menu
– Accumulate Data window, E–330
– Control screen, E–340
– Cumulative screen, E–334
– Individual QC Chart window, E–322
– Individual screen, E–320
– Install screen, E–344
– QC cumulative screen, B–217
– QC individual screen, B–209
– QC install screen, B–220
– QC run status screen, B–207
– QC status screen, B–202
– Realtime QC window, E–327
– Run Status screen, E–317
– Status screen, E–311
QC points
– adding comments, B–211
– excluding, individual points, B–211
QC Rack Assignment window
– buttons, E–343
– control list, E–342
– Control screen, E–342
QC request list
– print screen, E–147
– report, E–148
QC run status screen, B–207
QC Setting window, E–387
QC status, E–312
QC status screen, B–202
QC tab
– Print screen, E–129
– See also, QC menu.
QC violation, E–499
Qualification
– operator, A–6
Qualitative evaluation
– c 501 (ISE) tests, E–505
– photometric tests, E–505
– serum indexes, E–491
Qualitative fields
– photometric application parameters, B–273
Quality criteria
– calibration, e 601 module, B–164

R

R4SD (data alarm), D–57
Rack, A–59
– assigning QC rack, B–219
– barcodes, A–114
– rack delivery button, B–284
– rerun, assign or delete manually, B–87
– sample, A–59, A–117
– trays, A–59
– unloading QC racks from the rack rotor, B–229
Rack archival report
– print screen, E–175, E–178
– report example, E–176
– report explanation, E–176
Rack Assignment window
– description, E–367
– false bottom tube, E–370
– Module Setting tab (Utility), E–371
– Non-Standard Tube area, E–370
– Range Setting tab (Utility), E–368
– See also, Calibrator Rack Assignment window.
– See also, QC Rack Assignment window.
Rack Collect End
– status, B–233
Rack Collect End (Restart Disabled)
– status, B–233
Rack delivery
– button, B–284
Rack list, QC Rack Assignment, E–343
Rack reception mode, E–189
Rack registration, Inventory Update window, E–453
Rack Reset window, E–425
Rack rotor, A–58
Rack rotor, to inactivate, B–240
Rack sampler, A–53
– rack loader, A–54
– rack unloader, A–54
Rack sampler unit
– clean filter, C–57
Random error, realtime QC, D–57
Range Setting tab, Rack Assignment window, E–368
Range tab
– Default area, E–506, E–509
– displaying application parameters, E–503, E–507
– Expected Values area, E–506, E–509
– Qualitative area, E–505
– repeat limit, E–504, E–508
Reaction bath
– c 501 module, A–78
Reaction cell
– washing, c 501 module, B–300
Reaction cell rinse unit, c 501 module, A–80
Reaction disk, A–78
– c 501 module, A–77
– e 601 module (incubator disk), A–99

Reaction monitor
– report, E–86
Reaction monitor (Calibration)
– print screen, E–107
– selecting standards, E–107
Reaction monitor (Workplace)
– print screen, E–84
– report example, bichromatic, E–86
– report example, c 501 (P), E–85
– report explanation, E–86
Reaction Monitor window
– calibration, c 501 (P), E–289
– Scale Setting window, E–242
– Scale Setting window, c 501 (P), E–291
– Test Review window, E–240
Reaction monitoring
– c 501 module, A–85
Reaction system
– cell rinse nozzles, replace nozzle tips, C–106
– clean the cell cover, C–79
– replace reaction cells, C–86
– rinse the reaction system (c 501 module), C–77
– specifications, c 501 module, A–119
– specifications, e 601 module, A–122
Read Backup Disk window
– Data Review screen, E–222
Reag.F (data alarm)
– e 601 module, D–36
Reag.H (data alarm)
– e 601 module, D–37
Reag.S (data alarm)
– e 601 module, D–37
– ISE unit, D–17
Reag.T (data alarm)
– e 601 module, D–37
Reag.X? (data alarm), E–375
Reagent
– auxiliary reagents, c 501 module, A–87
– auxiliary reagents, e 601 module, A–106
– auxiliary, c 501 module, B–111
– auxiliary, e 601 module, B–122
– characteristics, D–62
– e 601 module application, B–114
– expired, alarm, E–375
– ISE application, B–105
– loading, safety information, A–12
– management system, A–75
– operator-related reagent management, B–124
– photometric application, B–108
– pipetter, c 501 module, A–73
– pipetting system, A–73
– Pretreatment, B–118
– probe, c 501 module, A–73
– Reagent Status report, E–101
– registration, manual, B–126
– reload, e 601 module, B–128
– replace, c 501 module, B–131
– replace, e 601 module, B–50, B–132
– replace, ISE unit, B–45
– software screen, B–23
– standby reagent QC, B–53, B–198, B–206
– storage compartment, c 501 module, A–72
– syringe, c 501 module, A–74
– trouble attributed, D–62
– types, E–253
Reagent barcode reader
– check report, E–185
– maintenance checks, E–470
Reagent Bottle Setting window, E–417
Reagent Capping window, e 601 module, E–460
Reagent compartment
– c 501 module, A–72
– e 601 module, A–97
– e 601 module, cleaning, C–146
– ISE unit, A–91
Reagent concept
– c 501 module, B–105
– e 601 module, B–114
Reagent Details list, Reagent > Status screen, E–261
Reagent disk
– cover does not open/close, e 601 module, D–85
– e 601 module, A–98
– e 601 module, cleaning, C–146
– See also, Reagent compartment.
Reagent disk temperature, D–37
Reagent Dump
– status, B–233
Reagent Level Check window
– Purple Alarm area, E–390
– Yellow Alarm area, E–389
Reagent Load List
– daily operation, B–45
– printing, B–45
Reagent Load/Unload List
– explanation, E–102, E–105
Reagent menu
– reagent setting screen, B–125
– reagent status screen, B–130
– Setting screen, E–251
– Status screen, E–259
Reagent overview button, B–124, B–141
Reagent Overview window
– consumables' status, E–27
– Detail window, E–37
Reagent overview window, B–141
– c 501 module, B–141
– e 601 module, B–147
Reagent Parameter Setting window
– Elecsys area, E–432
– ISE area, E–432
Reagent Pipetter Check window, e 601 module, E–476
Reagent Preparing, B–44

Reagent Prime window, E–256
Reagent probe
– c 501 module, A–73
– does not descend to liquid surface, D–73
– e 601 module, A–98
– special wash, Chemistry tab, E–529
– washing, c 501 module, B–298
– washing, e 601 module, B–304
Reagent Probe Wash window, e 601 module, E–445
Reagent Registration
– status, B–233
Reagent setting screen, B–124, B–125
Reagent Status report, E–101
Reagent status screen, B–124, B–130
Reagent storage
– c 501 module, A–72
– e 601 module, A–97
Reagent syringe
– bubbles in, D–73
– c 501 module, A–74
– e 601 module, A–98
Reagent system
– c 501 module, A–72
– specifications, c 501 module, A–120
– specifications, e 601 module, A–123
Reagent troubleshooting
– photometric unit, D–82
Reagent Unloading
– status, B–233
ReagEx (data alarm)
– e 601 module, D–36
– photometric unit, D–29
Realtime QC, B–197, B–212
– configuring realtime QC, B–212, B–215
Realtime QC window
– buttons, E–329
– QC menu, E–327
– Reject Data window, E–333
– Rule area, E–328
– Select Control window, E–331
– Select Rules window, E–332
– Yoden twin plot, E–328
Rear view
– c 501 module, A–88
Reassign
– control values, B–225
Reconnect
– status, B–233
Record space, E–207
Recovery of controls
– e 601 module, D–91
Reference cartridge
– ISE measuring system components, A–91
Registration
– c pack, B–109, B–116
– reagent, manual, B–126
Reject Data window, E–333
Reloading
– c pack, B–109
– reagent, e pack, B–128
Reloading check box
– test assignment, c 501 (P), E–547
– test assignment, e 601 module, E–548
Remedy, alarm, E–66
Repeat limit
– change, B–272
Repeat limit (data alarm)
– e 601 module, D–38
– ISE unit, D–18
– photometric unit, D–29
Repeat Limit Flag, check box, E–374
Repeat limit, application parameters, E–504, E–508
Repeat Test Selection window
– Last Rack No. Pos., E–215
– Last Sequence No., E–215
Replace photometer lamp
– Change Light Source Lamps window, E–464
Replacement
– periodic replacement of parts, c 501 module, C–67
Replacing
– AssayCup, B–139
– AssayTip, B–139
– CleanCell when empty, B–132
– CleanCell when not empty, B–135
– consumables, e 601 module, B–139
– magazine, B–139
– PreClean when empty, B–134
– PreClean when not empty, B–137
– ProbeWash when empty, B–135
– ProCell when empty, B–132
– ProCell when not empty, B–135
– ProCell/CleanCell, D–85
– reagent, c 501 module, B–131
– reagent, e 601 module, B–132
– reagent, ISE unit, B–45
– reagents, e 601 module, B–50
Report
– customize, B–306
– maintenance report, C–22
– name, B–271
– page length, E–540
– page/sample, E–540
– print order, E–543
– report/page, E–540
– title, E–541
Report format
– comparison of data monitor format and report format, B–309
– configuration, B–306
Report Format screen
– Caracter-Line-Column list, E–541
– description, E–540

– Print Order area, E–543
Report print buffer, E–70
Reports
– Alarm Trace, E–149
– Application Parameters, E–161
– Calibration Request List, E–119
– Calibration Trace, E–111
– Calibrator Load List, E–109
– Cell Blank, E–165
– Communication Trace, E–154
– Cumulative Operation List, E–158
– Cumulative QC Chart, E–138
– Cumulative QC List, E–142
– Cuvette History, E–171
– Data Print, E–77
– Individual QC Chart, E–129
– Individual QC List, E–135
– Maintenance Report, E–167
– Operator ID Trace, E–156
– Precision Check, E–95
– Profile List, E–97
– QC Load List, E–144
– QC Request List, E–147
– Rack Archival Report, E–175, E–178
– Reaction Monitor (Calibration), E–107
– Reaction Monitor (Workplace), E–84
– Reagent Status report, E–101
– Report Example, E–163
– Requisition List, E–88
– Rerun List, E–92
Reports, automatically generated
– Backup Disk, E–182
– Barcode Reader Check, E–184
– Calibration Monitor, E–121
– Hard Disk Check, E–179
– Reagent Barcode Reader Check, E–185
– Sample Barcode Reader Check, E–184
Reports, backup on disks, E–74
Reports, from Utility > Maintenance, E–179
Reports, table of, E–75
Reproducibility, poor, D–61
Requesting
– calibrations, B–53
– controls, B–53
– QC measurement, B–205
– tests manually, B–83
Requisition list
– print screen, E–88
– report, E–90
Rerun
– automatic, B–67
– Automatic Rerun check box, E–504, E–508
– list, D–63
– manual, B–68
– performed by system, B–67
– processing, B–67
– rack, assign or delete manually, B–87
– with diluted samples, B–68
Rerun list
– print screen, E–92
– report, E–93
Rerun Rack Assignment window
– button, E–214
– Test Selection screen, E–214
Reset window, E–424
Restoring
– system parameters, B–312
Result data
– at high level, D–61
– at low level, D–61
– drifting, D–60
Results
– 3rd Results Acceptance, B–280
– accumulation of QC results, B–215
– biased enzyme, D–84
– checking calibration and QC, B–57
– erratic, e 601 module, D–86
– erratic, ISE unit, D–74
– printing individual, B–72
– ready for validation, B–70
Review Alarm screen, B–34
Review by Exception window, E–419
Reviewing
– calibration data, B–169
Rinse station
– c 501 module, cleaning, C–81
– e 601 module, cleaning, C–134
– ISE unit, c 501 module, A–91
– microbead mixer rinse station, e 601 module, A–97
– PreClean area, e 601 module, A–101
– reagent probe rinse station, e 601 module, A–97
– reagent probe rinse stations, c 501 module, A–74
– sample probe rinse station, c 501 module, A–71
– sample probe rinse station, e 601 module, A–99
– sipper probe rinse station, e 601 module, A–99
Roche service representative, calling, D–68
Routine operation
– procedures, B–61
– workflow, B–29
Routine QC, B–198
Routine QC test selection, E–387
Routine QC window
– routine QC list, E–313
– Status screen, E–313
Rsp1.E (data alarm)
– ISE unit, D–48
Rsp2.E (data alarm)
– ISE unit, D–48
Rules
– calibration, c 501 module, B–158
– calibration, e 601 module, B–162

Run
– start a run, B–64
Run Status screen
– chart, E–319
– details, E–318
– QC menu, E–317
– run status, E–317

S

S. Stop screen, E–64
S10Xa (data alarm), D–59
S10Xw (data alarm), D–59
S1A.E (data alarm)
– photometric unit, D–48
S2-2Sa (data alarm), D–58
S2-2Sw (data alarm), D–58
S4-1Sa (data alarm), D–58
S4-1Sw (data alarm), D–59
Safety
– electrical, A–11
– mechanical, A–12
Safety classifications, A–5
Safety information
– barcode readers, A–30
– general safety information, A–3
Safety labels, A–22
– front view, A–24
– rear view, A–29
– side view, A–26
– top view, A–27
Safety precautions, A–6
Samp.? (data alarm)
– photometric unit, D–30
Samp.B (data alarm)
– e 601 module, D–38
Samp.C (data alarm)
– e 601 module, D–38
– ISE unit, D–18
– photometric unit, D–30
Samp.H (data alarm)
– e 601 module, D–39
Samp.O (data alarm)
– c 501 module, D–30, D–39
Samp.S (data alarm)
– e 601 module, D–39
– ISE unit, D–18
– photometric unit, D–31
Sample
– additional, B–65
– barcode, unreadable, B–86
– barcodes, A–114
– clot (data alarm), e 601 module, D–38
– concentration, decreased/increased, D–63
– container, A–61, A–116
– cup, A–61
– hovering (data alarm), e 601 module, D–39
– identification, A–62
– insoluble contaminants, safety information, A–14
– loading routine samples, B–63
– loading STAT sample, B–66
– loading, safety information, A–12
– pipetter, c 501 module, A–70
– prediluted, B–69
– processing, B–62
– processing STAT sample, B–65
– rack, A–59
– racks, specifications, A–117
– rerun, B–67
– reruns with diluted samples, B–68
– results, B–70
– selecting test, B–65
– tracking sample on analyzer, B–98
– troubleshooting, photometric unit, D–82
– tube, A–61
– unreadable barcode, B–86
Sample area
– Barcode Read Error window, E–213
– Filter window, E–225
– Test Selection screen, E–204
Sample barcode reader
– check report, E–184
Sample barcode reader (sample identification), A–62
Sample clogging (data alarm)
– ISE unit, D–18
Sample clot (data alarm)
– e 601 module, D–38
Sample count, E–217
Sample Data Clear, B–44
– window, E–11
Sample information, Demographics window, E–211
Sample Pipetter Check window, e 601 module, E–475
Sample probe
– c 501 module, A–70
– e 601 module, A–99
– not descending to liquid surface, D–73
– washing, c 501 module, B–302
– washing, e 601 module, B–305
Sample rack, A–59
Sample search, B–98
Sample Search window
– description, E–24
Sample selection list, Data Review screen, B–89, B–96, E–218, E–246
Sample status, E–207
Sample syringe
– bubbles in, D–73
– c 501 module, A–71
– e 601 module, A–100
Sample Tracking button, B–60

Sample Tracking window, B–98
– buttons, E–23
– description, E–17
– Others view, E–21
– Position Status area, E–20
– Rack Information area, E–19
– Rack Monitor area, E–18
Sample Tracking, System Overview screen, E–7
Sample volume
– application parameters, E–487
Sample volumes
– minimum, c 501 module, A–119
Sampling stop, B–73
Sampling system
– specifications, c 501 module, A–119
– specifications, e 601 module, A–122
Saving
– print view buffer contents, E–74
Scale Setting window
– manual/automatic options, E–242
– reaction monitor, E–242
– reaction monitor, c 501 (P), E–291
– working information, c 501 (P), E–286
Screen
– accessibility, B–10
– alarm screen, B–34
– calibration, B–24
– calibration calibrator, B–178
– calibration install, B–181
– calibration status, B–166
– cannot access another screen, D–72
– data review, B–88, B–96
– general description, B–5
– guidance prompt, B–6
– menu tabs, B–7
– QC, B–25
– QC cumulative, B–217
– QC individual, B–209
– QC install, B–220
– QC run status, B–207
– QC status, B–202
– reagent, B–23
– reagent setting, B–124, B–125
– reagent status, B–124, B–130
– start screen, B–64
– status line, B–6
– system overview, B–21, B–194
– utility, B–26
– workplace, B–22
SD limit, application parameters, E–497
SD.E (data alarm)
– photometric unit, D–49
Search Sample window
– Data Review screen, E–223
– Find area, E–223
– Search area, E–224
– Search Option area, E–224
Searching, Online Help, B–16
Second rotor module
– module overview, A–41
Select Chart window
– buttons, E–326, E–339
– Control Lot No. list, E–326, E–339
– Cumulative QC Chart window, E–339
– Individual QC Chart window, E–326
– Plot list, E–326, E–339
Select Control window
– Control Lot No. list, E–331
– Plot list, E–331
– Realtime QC window, E–331
Select Rules window
– Realtime QC window, E–332
– Rules area, E–332
Selecting
– items on touchscreen, A–46
– power up pipe, C–15
– sleep pipe, C–17
– start up pipe, C–16
– test, B–62, B–65
Selecting tests, start-up calibration, B–177
Send To Host window
– Data Review screen, E–227
– Data Type area, E–227
– Run Type area, E–228
– Test Host Status area, E–227
Sens.E (data alarm)
– photometric unit, D–49
Sensitivity limit, c 501 application parameters, E–497
Serum index
– define factors, E–491
– qualitative evaluation, E–491
Setting screen
– buttons, E–254
– Module list box, E–251
– Reagent menu, E–251
– setting screen list, E–252
Shewhart, multi-rule, E–332
Shortcut keys, B–11
Shut Down
– status, B–233
Shut down screen
– Log off, E–59
– Shutdown, E–60
– Sleep, E–59
Shutdown
– maintenance after shutdown, B–76
– maintenance before shutdown, B–74
Sig.E (data alarm)
– e 601 module, D–50
Signal
– maximum (data alarm), e 601 module, D–50
– minimum (data alarm), e 601 module, D–50

Sipper
– mechanism, ISE unit, A–90
– PreClean area, e 601 module, A–101
– probe for measuring cells, e 601 module, A–100
– syringe, e 601 module, A–100
Sipper Air Purge window, e 601 module, E–449
Sipper Check window, e 601, E–481
Sleep
– status, B–233
Sleep mode, B–75
Sleep pipe, selecting, C–17
SLLD.E (data alarm)
– e 601 module, D–40
SLLD.N (data alarm)
– e 601 module, D–40
Slop.E (data alarm)
– ISE unit, D–51
Sodium
– high value, D–77
– ion-selective electrode, A–91
Software
– basics, B–3
– calibration screen, B–24
– cannot access screen, D–72
– check sum, E–467
– general description, B–5
– main menu screens, B–21
– QC screen, B–25
– reagent screen, B–23
– screen accessibility, B–10
– utility screen, B–26
– version, E–467
– workplace screen, B–22
Software basics, B–3
– menu tabs, B–7
– windows, B–10
Software version
– determining, C–43, E–466, E–467
Solid waste
– clean compartment, e 601 module, C–148
– container, e 601 module, A–105
– e601 module, B–139
– empty, e 601 module, B–140
Solutions
– reagents and cleaning solutions, c 501 module, A–87
– reagents and cleaning solutions, e 601 module, A–106
Sound Setting window, E–67
Sound, abnormal, A–20
Special wash, B–297
– programming, c 501 module, B–297
– programming, e 601 module, B–304
Special Wash screen, E–528
Specifications
– c 501 module, A–119
– core unit, A–118
– e 601 module, A–122
– ISE unit, A–121
– photometric unit, A–120
– reaction system, c 501 module, A–119
– reaction system, e 601 module, A–122
– reagent system, c 501 module, A–120
– reagent system, e 601 module, A–123
– sample containers, A–116
– sample racks, A–117
– sampling system, c 501 module, A–119
– sampling system, e 601 module, A–122
– system, A–111
Spillage, safety precaution, A–20
Stand By
– status, B–233
Stand By Bottle QC window
– buttons, E–315
– stand by bottle QC list, E–314
– Status screen, E–314
Standard buttons, B–9
Standby bottle QC *see also* Standby reagent QC
Standby reagent QC, B–53, B–198, B–206
Start
– analyzer, B–30
– inspection, B–30
– measurement, B–64
– processing samples, B–64
– screen, B–64
Start a run, B–64
Start Conditions screen
– Automatic Rerun area, E–188
– Default Profile Per Sample Type window, E–198
– description, E–186
– Host setting area, E–188
– Masking Window, E–195
– Module Masking window, E–197
– rack reception mode, E–189
– Star Sample No. area, E–187
– Start Up Pipe Setting area, E–187
Start Up Pipe
– status, B–233
Start up pipe, selecting, C–16
Start Up Setting window, E–294
– Method area, E–295
– Start Up list, E–295
Starting inspection, B–30
STAT
– loading STAT sample, B–66
– port, core unit, A–55
– processing STAT sample, B–65
– requesting test manually, B–85
– selecting test, B–65
Status
– backup wait for rack setting, B–233
– initialize, B–233
– instrument, B–233
– maintenance, B–233

– operation, B–233
– parameter check, B–233
– pipe, B–233
– post operation, B–233
– power up, B–233
– power up pipe, B–233
– preparation, B–233
– rack collect end, B–233
– rack collect end (restart disabled), B–233
– reagent dump, B–233
– reagent registration, B–233
– reagent unloading, B–233
– reconnect, B–233
– shut down, B–233
– sleep, B–233
– stand by, B–233
– Start up pipe, B–233
– stop, B–233
Status line, B–6
– color scheme, B–37
– instrument status, B–233
Status list
– Calibration > Status screen, E–268
– QC > Status screen, E–311
Status screen (Calibration)
– buttons, E–270
– Calibration menu, E–267
– Method area, E–269
– Position/Test list, E–268
Status screen (QC)
– buttons, E–312
– QC menu, E–311
– Routine QC window, E–313
– Stand By Bottle QC window, E–314
– Status list, E–311
Status screen (Reagent)
– button, E–263
– Inventory list, E–262
– Module list box, E–259
– reagent details list, E–261
– Reagent menu, E–259
– test list, E–260
Std.E (data alarm)
– photometric unit, D–52
Stop
– sampling, B–73
– shutdown analyzer, B–74
– status, B–233
Stop screen, E–58
Support
– calling Roche service representative, D–68
Syringe
– bubbles in, D–73
Sys.E (data alarm)
– e 601 module, D–54
SysClean
– e 601 reagents, B–122
– liquid flow path cleaning, C–137
SysR.S (data alarm)
– e 601 module, D–41
SysR.T (data alarm)
– e 601 module, D–41
System
– c 501 module characterristics, A–67
– configuration, B–277
– e 601 module characteristics, A–95
– implementations for QC measurements, B–198
– manual start-up, B–33
– Online Help, B–13
– reagent management, A–75
– reagent, c 501 module, A–72
– safety labels, A–22
– specifications, A–111
– status, B–233
System Air Purge window
– Channel area, E–462
– e 601 maintenance, E–462
System communication trace report
– See, communication trace report
System modules, overview, A–36
System Overview
– icon, E–57
System Overview screen, B–21, B–194, E–5
– color scheme, module overview area, B–39
– color scheme, Work Flow Guide, B–37
– Main menu buttons area, E–10
– Module Overview area, E–8
– operation, B–35
– preventive action, B–40
– Work Flow Guide, B–40, E–6
System parameters
– 3rd Results Acceptance, B–280
– programming, B–278
– restoring, B–312
– saving, B–310
– stored by Parameter Read/Write, B–311
System Prime (e 601) window, E–463
System screen (Utility), E–361
System specifications, A–111
System Wash window, E–444
System wash, maintenance item, C–41

T

Target mean
– cumulative QC, E–352
– individual QC, E–352
Target SD
– cumulative QC, E–352
– individual QC, E–352

Technical limit
– application parameters, E–504
– change, c 501 module, B–272
– data alarm, e 601 module, D–41
Test
– 3rd Results Acceptance, B–280
– activate control tests, B–227
– assigning tests or profiles to test keys, B–281
– assigning to module, B–288
– calculated test, B–291
– calibrating tests during operation, B–194
– calibrations points, D–83
– checking calibrations of e 601 tests, B–174
– checking calibrations of ISE tests, B–173
– checking calibrations of photometric tests, B–169
– compensated test, B–295
– define automatic rerun, e 601 module, B–271
– define report name, e 601 module, B–271
– high results, photometric unit, D–78
– immunological tests, B–251
– low results, photometric unit, D–79
– multiple photometric tests, D–83
– photometric tests, B–251
– request manually, B–83
– selecting tests for start-up calibration, B–177
– single test, D–82
– trouble, D–62
Test Assignment window, E–545
– c 501 (P), E–546
– e 601, E–547
Test Count Write window, E–441
Test Key Assignment window, E–385
Test list
– Edit Calibrator window, E–308
– Edit Control window, E–352
– Host Test Code Setting window, E–382
– QC > Install screen, E–345
– Reagent > Status screen, E–260
– Utility > Application screen, E–484
Test matrix, B–81, E–208
– colors, B–81, E–208
– Key Setting window, E–384
– markings, B–82, E–209
– test selection screen, B–81
Test priority, e 601 test parameter, E–507
Test results list
– Data Review screen, B–90, B–97, E–219, E–247
– Test Review window, E–233, E–236
Test Review window
– buttons, E–237
– Data Review screen, E–232, E–235
– Manual Test window, E–239
– Reaction Monitor window, E–240
– Sample data area, E–232, E–235
– Test result list, E–233, E–236
Test selection
– downloaded form Host, B–62
– for STAT samples, B–65
– manual selection, B–83
Test Selection screen, E–203
– Barcode Read Error window, E–213
– buttons, E–210
– fields, E–204
– Repeat Test Selection window, E–215
– Rerun Rack Assignment window, E–214
– Sample area, E–204
– test matrix, E–208
Test selection screen
– colors, B–81
– markings, B–82
– overview, B–80
– test matrix, B–81
Text boxes, software basics, B–7
Third-party software, A–19
Timeout
– application parameters, E–504, E–508
– QC status, E–312
Timeout QC, B–198, B–204
Tip
– See, AssayTip.
Touchscreen
– does not come on, D–72
– hard to see, D–72
– monitor, A–46
Trace Doc
– Trace Doc Export window, E–465
Track samples, B–98
Tray, A–59
Trouble
– attributed to characteristics of reagent, D–62
– for each test, D–62
– on each analytical module, D–62
– on each channel in same module, D–62
Troubleshooting, D–65
– application, D–67
– barcode read error, B–86
– c 501 module, D–68, D–74, D–78
– computer, D–67
– e 601 module, D–69, D–85
– general, D–67
– immunoassay, D–69
– instrument, D–70
– ISE unit, D–74
– operator's responsibility, D–68
– photometric tests, D–84
– photometric unit, D–78
– Power Up, D–70
– procedures, D–67
Tube, A–59
– sample, A–61

U

Ultrasonic mixer
– c 501 module, reaction disk area, A–78
– clean the ultrasonic mixers, C–98
– data alarms, D–27
Unit of measure
– change for an application after calibration, B–269
– defining, B–269
– list box, E–503, E–507
Unloading
– c pack, B–109, B–127
– QC racks from the rack rotor, B–229
Unreadable sample barcodes, B–86
Update
– inventory, E–47
Updating
– application, B–258
– inventory, e 601 module, B–151
USB device, B–247
USB storage device, A–18
User interface
– buttons, B–8
– check boxes, B–8
– general description, B–5
– list boxes, B–7
– main menus, B–21
– menu tabs, B–7
– option buttons, B–8
– text boxes, B–7
Utility > System screen
– Barcode Setting area, E–362
– Date/Time area, E–362
– Other area, E–363
– Printer area, E–362
– Rack Assignment area, E–362
– Screen Saver Setting area, E–363
– Wash Rack Sampling area, E–364
Utility tab
– Print screen, E–149
– See also, Utility menu.
Utility, software screen, B–26

V

Vacuum system, c 501 module, A–87
Vacuum tank, C–109
Validating
– calibration, B–57
– QC, B–57
Value
– edit concentration value, B–189
– edit control value, B–224
– expected value ranges, B–274
– high sodium, D–77
– internal standard, high/low, D–76
– low chloride, D–77
– low ISE values, D–77
– reassign control values, B–225
Values
– expected, application parameters, E–506, E–509
Variances
– among e modules, D–92
Version
– software, E–467
Volume control
– c pack, B–109, B–116
Vortex mixing station, A–102
– clean, C–130
– e 601 module, A–104

W

Wash rack
– See, Green rack.
Wash Reaction Parts window, E–430
Waste
– cleaning drain port (c 501 module), C–76
– compartment, e 601 module, A–105
– emptying solid waste, e 601 module, B–140
– safety information, A–11
– solid waste container, e 601 module, A–105
– solid, e 601 module, B–139
Water leakages, A–20
Water supply, A–57
Water tank, C–53
Wavelength
– defining, application parameters, E–487
Wavelengths, photometric unit, A–120
WB.S (data alarm)
– e 601 module, D–42
WB.T (data alarm)
– e 601 module, D–42
Westgard algorithm, E–332
Windows
– confirmation, B–10
– software basics, B–10
With Automatic Rerun, check box, E–374
With Reagent Registration
– Inventory Update window, E–453
Work Flow Guide
– area, B–40
– color scheme, system overview screen, B–37
– guide through preventive action, B–40
– System Overview screen, E–6
Working Information window
– c 501 (P), E–284
– Scale Setting window, c 501 (P), E–286
Workplace
– software screen, B–22

Workplace menu
– Data Review screen, E–216
– data review screen, B–88, B–96
– Test Selection screen, E–203
– test selection screen, B–80
Workplace tab
– Print screen, E–77
– See also, Workplace menu.

X

X-R, B–199

Y

Yoden twin plot, E–328

Notes H